IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

In re REMICADE ANTITRUST LITIGATION This Document Relates To: ALL ACTIONS. NATIONAL EMPLOYEES HEALTH PLAN, LOCAL 295 IBT EMPLOYER GROUP WELFARE FUND and THE WELFARE FUND OF PLUMBERS LOCAL UNION NO. 200, Individually and on Behalf of All Others Similarly Situated, Plaintiffs, vs. JOHNSON & JOHNSON and JANSSEN BIOTECH, INC., Defendants.	Civ. Action No. 2:17-cv-04326-JCJ CLASS ACTION The Honorable J. Curtis Joyner CONSOLIDATED AMENDED COMPLAINT FOR VIOLATIONS OF THE SHERMAN ANTITRUST ACT, THE CLAYTON ACT AND STATE ANTITRUST AND CONSUMER PROTECTION STATUTES DEMAND FOR JURY TRIAL

INTRODUCTION

1. In an effort to maintain and extend its monopoly in the market for its powerhouse biologic medication, Remicade (a.k.a. infliximab), Johnson & Johnson ("J&J") and Janssen Biotech, Inc. ("Janssen"), a wholly owned subsidiary of J&J,[1] worked to suppress competition and raise prices to purchasers of the biologic by imposing a web of exclusionary contracts on both health insurers and healthcare providers. In addition to the exclusionary contracts, the company also engaged in other anticompetitive acts, including bundling other J&J products with Remicade, implementing coercive rebate policies and filing sham patent litigation. These acts, each anticompetitive on their own, were magnified when used in concert and all served to maintain J&J's stranglehold on the market, maintain its grasp on the nearly $5 billion annual market for the medication, and shut out would-be competitors whose entrance into the market would naturally cause prices for the important drug to decline. Using its monopoly power, J&J forced health insurance companies and healthcare providers to enter into exclusionary agreements that effectively blocked competition for Remicade, thus causing Plaintiffs and members of the Classes (as defined below) to overpay on their infliximab purchases.

2. According to the U.S. Food and Drug Administration ("FDA"), "Biological products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins." In general, biologics are at the "forefront of biomedical research, and may be used to treat a variety of medical conditions for which no other treatments are available." Biologics are genetically engineered proteins derived from human genes, typically injected into the bloodstream. They are manufactured in a living system, such as a microorganism or plant or animal cells, by combining genetic material from multiple sources.

[1] Plaintiffs here refer to J&J and Janssen as Defendants and as J&J.

3. For most uses, at list price Remicade sells for about $4,000 per infused dose and about $26,000 for a full year of treatment. The drug (and its biosimilar competitors) is designed to inhibit specific components of the immune system that play pivotal roles in fueling inflammation. These drugs are used to treat many afflictions, including rheumatoid arthritis and Crohn's disease. Remicade is given by intravenous infusion in the doctor's office, an infusion center or hospital. Each infusion takes about two hours. The intravenous treatments are generally given three times during the first six weeks of therapy, then every eight weeks thereafter.

4. For years, J&J enjoyed patent protection on its blockbuster biologic, but that protection was limited under federal patent law. With the expiration of its patent, two Remicade biosimilars *(i.e.*, a generic version of a biologic) have been brought to market.[2] On April 5, 2016, Pfizer, Inc. ("Pfizer"), in partnership with Celltrion, received FDA approval for the biosimilar Inflectra (infliximab-dyyb). Pfizer began shipping Inflectra in November 2016 at a 15 percent discount to the wholesale acquisition cost ("WAC") of Remicade. On April 17, 2017, the FDA approved Merck and Samsung Bioepsis' ("Samsung") biosimilar, Renflexis (infliximab-abda). Merck began selling Renflexis in July 2017 at a 35 percent discount to the list price of Remicade. Pfizer similarly adjusted its list price on Inflectra in response.

5. Despite offering large price discounts, these new entrants in the market have garnered only a *de minimus* share of the market because of J&J's successful exclusionary scheme.

6. Pfizer received FDA approval for a second Remicade biosimilar in December 2017, but Pfizer said it will not launch Ixifi in the United States. Because of J&J's actions in relation to Inflectra, it is unsurprising that Pfizer is being cautious about launching another biosimilar in the

[2] Remicade consists of monoclonal antibodies bioengineered from mouse tumors. Remicade is a live, large molecule protein.

United States. Meanwhile Plaintiffs and members of the Classes are deprived of choice in the marketplace.

7. Within weeks of its competing product's launch, J&J began to deploy what it has publicly termed its "Biosimilar Readiness Plan." The core features of the plan are exclusionary contracts that foreclose Pfizer's access to an overwhelming share of consumers, coupled with anticompetitive bundling and coercive rebate policies designed to block both insurers from reimbursing and hospitals and clinics from purchasing Inflectra or other biosimilars of Remicade despite their lower pricing. Pfizer has sued J&J in federal court for this wrongful conduct.[3]

8. J&J's actions to maintain its position took several forms. It entered into exclusive contracts with insurance companies. Insurer decisions regarding reimbursement policies have a dramatic impact on which infliximab product will be stocked by healthcare providers such as hospitals and clinics. Because providers administer infliximab on site (it is an infusion product), they must use their own funds to stock the product, purchasing it for later use and relying upon subsequent reimbursement from insurers to recoup their expenses. Given the cost of biologic drugs generally, and Remicade in particular, there is almost no chance that providers will pay for a product that is not widely covered by insurers for fear of stocking a product that will not be reimbursed after the provider administers it to a patient, as even a single unreimbursed dose may cost the provider in excess of $4,000. J&J induced insurers to enter into contracts that require an explicit commitment not to cover Inflectra at all or to do so only in the rarest of circumstances – in effect, to make Remicade the only covered infliximab.

9. As a direct result of these exclusive dealing contractual commitments, Pfizer alleges, Inflectra is either not listed on the insurance company's medical policy – a published listing of the

[3] As discussed below, J&J brought suit against Samsung for its competing product, but that case was recently dismissed with prejudice by J&J.

drugs approved for reimbursement under the insurer's medical benefit – or is designated reimbursable only in so-called "fail first" cases. The "fail first" exception, which requires that Remicade has been tried by and failed with respect to a given patient before a biosimilar infliximab can be reimbursed, is medically inappropriate and illusory in practice. Because the drugs are biosimilars, if Remicade, which is an infliximab product, does not work for a patient, a physician would turn to a non-infliximab drug, not to Inflectra, which is also an infliximab product and has no clinically meaningful differences from Remicade. Years of clinical trials submitted to the FDA have shown no meaningful difference in treatment outcome between Remicade and Inflectra.

10. J&J has also excluded competition by offering exclusionary rebates and bundling arrangements with insurance company payers. One way that J&J has been able to coerce insurers into accepting the exclusionary contract terms noted above is by denying rebates to insurers that decline J&J's exclusivity commitments, thereby imposing a substantial financial penalty. Insurers that decline J&J's offer face a substantial financial penalty, and those that accept receive a payoff (multimillion dollar rebate payments) in return for their commitment to exclude biosimilars. Notably, unlike generic drugs, which can be substituted without a new prescription, biosimilars require prescriber approval for changes.

11. The head of J&J's pharmaceuticals business told investors that "the 70% of patients who are [already] stable on Remicade are highly unlikely to switch." Even if this unsubstantiated claim were true, it means that 30 percent of the $5 billion would be up for grabs in a competitive market. But instead, J&J avoided competition by bundling this economically "incontestable" demand for Remicade with the portion of demand that was and is "contestable" (that is, new patients starting therapy with infliximab or patients who may switch to the lower cost biosimilars) by threatening to deny rebates on all Remicade prescriptions if any infliximab biosimilars are reimbursed. This had the intent and effect of forcing insurers to forfeit rebates if they chose to

prescribe the biosimilar and forced insurers to pay J&J for whatever it wanted to charge for Remicade.

12. Pfizer also alleges that J&J bundles rebates on multiple different products, such that insurers that refuse to grant exclusivity to Remicade would be forced to pay higher prices and/or forego enhanced portfolio rebates. The net effect of these anticompetitive bundling practices is that the insurers subject to them have no real choice but to agree to J&J's exclusivity conditions. Pfizer alleges that insurers have led it to understand that the net cost for its version, Inflectra, would need to be low enough to offset the cumulative loss of J&J rebates. Further, Pfizer claims that it and Samsung cannot feasibly make up the difference for the J&J rebates on the existing Remicade patient base that insurers would lose if they declined the conditions imposed by J&J. Insurance companies that might want to reimburse Inflectra and Renflexis purchases cannot do so without incurring a substantial financial penalty imposed by J&J and thus potentially placing themselves at a disadvantage relative to insurers accepting J&J's rebates.

13. The effect of J&J's conduct is magnified because, given the gaps in insurance coverage between Inflectra (Pfizer's product) and Remicade, Pfizer alleges that providers have overwhelmingly chosen to stock only Remicade (which is essentially universally covered given its long tenure and dominant position) rather than deal with the risk of possible denials of coverage for Inflectra. Thus, providers have declined to purchase Inflectra across the board, even for patients covered by insurance plans that do cover the product.

14. Medicare covers Inflectra (and Renflexis), but Pfizer charges that providers have been unwilling to stock Inflectra even for potential use with such government-insured patients. It is likely that Samsung's product faces the same stocking issues. As a result, the government continues reimbursing for Remicade, the more expensive product. As of September 1, 2017, about 90 percent of healthcare provider accounts using infliximab had purchased no Inflectra at all. Despite some

coverage by regional and government plans, Inflectra has secured less than 4 percent of total infliximab unit sales in the United States as of September 1, 2017, according to Pfizer.

15. With entry into the market of a competitor, prices of the incumbent biologic should have fallen. Instead, the opposite has occurred. Since the time the FDA approved Inflectra and J&J implemented its publicly stated plan to block biosimilars like Inflectra, J&J has raised the list price of Remicade by close to 9 percent and increased the amount the U.S. government reimburses for Remicade by more than $190 per infused dose. J&J's list price increases are not overcome by increased rebates and discounts: Remicade's "average selling price" ("ASP") – which by federal law is an average of a drug's pricing after taking into account discounts, rebates and other price concessions – has actually increased since Inflectra's entry. As of September 2017, Remicade's ASP was more than 10 percent higher than Inflectra's ASP.

16. J&J has touted its success, noting that it had not "seen much of an impact" from Inflectra's entrance, and that J&J is "especially well-prepared to manage through the Remicade biosimilars." J&J also said it was confident that it could fend off even subsequent biosimilar entrants, including Renflexis, because of its exclusionary contracts: "[W]e have our contracting in place with all the managed care organizations [*e.g.*, health insurers]." The result is that Plaintiffs (along with healthcare providers and the U.S. government) have fewer choices and pay more than they should.

17. In addition to Defendants' multi-headed scheme, the Defendants' conduct related to the patent on Remicade is an additional anticompetitive basis that was the cause of inflated costs for which Plaintiffs seek relief. On January 23, 2018, the U.S. Circuit Court of Appeals for the Federal Circuit upheld a decision from the Patent Trial and Appeal Board that found J&J's sham patent litigation against Pfizer was barred under the doctrine of "obviousness-type double patenting." Under this decision, the court found that the patent covering the active ingredient in Remicade was

invalid because its concepts were covered in a prior J&J patent. As a result, J&J lost its ability to seek damages from Pfizer related to its biosimilar Inflectra product. This decision was hailed by Pfizer, with a spokesperson stating that "a key patent that J&J has asserted to block access to Inflectra is invalid." J&J, on the other hand, expressed the company was "disappointed" with the ruling. J&J's conduct in relation to the patent is separately actionable.

PARTIES

18. Plaintiff National Employees Health Plan (the "Plan") is an "employee welfare benefit plan" under ERISA and a jointly managed multi-employer plan under NLRA. It represents thousands of employees and their dependents across the country, principally in Michigan and Florida, on whose behalf health and other benefits are provided on a self-funded and insured basis. Medical benefits on a self-funded basis are provided through Blue Cross Blue Shield of Michigan and pharmaceutical benefits on a self-funded basis are provided through OptumRx. Member bills for prescriptions are paid by the Plan to its pharmacy benefits manager. The Plan is not generally aware from what source OptumRx purchases its products. The Plan is headquartered in Michigan. Plan participants from states including Ohio, Florida, Indiana, Delaware, West Virginia, Kentucky and Illinois were dispensed Remicade and paid or had paid on their behalf the required co-payment.

19. Plaintiff Local 295 IBT Employer Group Welfare Fund ("Local 295") is a union representing air freight chauffeurs, handlers, warehousemen, allied workers and other industrial employees. It is an "employee welfare benefit plan" under the Employee Retirement Income Security Act ("ERISA") and a jointly managed multi-employer plan under the National Labor Relations Act ("NLRA"). It represents thousands of employees and their dependents across the country on whose behalf health and other benefits are provided on a self-funded and insured basis. Local 295 is headquartered in New York. Plan participants in various states were dispensed Remicade and paid or had paid on their behalf the required co-payment.

20. The Welfare Fund of Plumbers Local Union No. 200 ("Welfare Fund") is an "employee welfare benefit plan" under ERISA and a jointly managed multi-employer plan under NLRA. It represents hundreds of employees and their dependents in the State of New York on whose behalf health benefits are provided on a self-funded and insured basis. Medical benefits on a self-funded basis are provided through MagnaCare and pharmaceutical benefits on a self-funded basis are provided through Express Scripts. The Welfare Fund is not generally aware from what source Express Scripts purchases its products. The Welfare Fund is headquartered in Ronkonkoma, New York. During the period from April 5, 2016 to the present the Welfare Fund paid for or made reimbursement for Remicade on behalf of participants who received Remicade treatment in various states including New York. Local 295, Plan and Welfare Fund are collectively referred to herein as "Plaintiffs."

21. Defendant Johnson & Johnson ("J&J") is a corporation organized and existing under the laws of New Jersey. J&J's principal place of business in the United States is located at One J&J Plaza, New Brunswick, NJ 08933. J&J is an international pharmaceutical company – one of the largest in the world – and was the sole supplier of infliximab, marketed as Remicade, between 1998 and 2016, when Inflectra came to market.

22. Defendant Janssen Biotech, Inc. ("Janssen") is a wholly owned subsidiary of J&J. Janssen is a corporation organized and existing under the laws of Pennsylvania. Janssen's corporate headquarters are located at 800 Ridgeview Drive, Horsham, Pennsylvania 19044. Janssen co-owns or has licenses to the Remicade patents and performs the marketing for Remicade in the United States.

23. All of the parties listed above as Defendants are collectively referred to herein as "Defendants."

JURISDICTION AND VENUE

24. This Court has original federal question jurisdiction over the Sherman Antitrust Act claim asserted herein, pursuant to 28 U.S.C. §§1331 and 1337, and §§4 and 16 of the Clayton Act, 15 U.S.C. §§15 and 26. This Court also has jurisdiction over this case pursuant to 28 U.S.C. §1332(d) and the Class Action Fairness Act of 2005 ("CAFA") (28 U.S.C. §1711, *et seq*.), which vests original jurisdiction in the district courts of the United States for any multi-state class action where the aggregate amount in controversy exceeds $5 million and where the citizenship of any member of the class of plaintiffs is different from that of any defendant. The $5 million amount in controversy and diverse citizenship requirements of CAFA are satisfied in this case.

25. Venue is proper in this District pursuant to §12 of the Clayton Act (15 U.S.C. §22), and 28 U.S.C. §§1391(b)-(d), because a substantial part of the events giving rise to Plaintiffs' claims occurred in this District, a substantial portion of the affected interstate trade and commerce discussed below has been carried out in this District, Defendants reside in, are licensed to do business in, are doing business in, had agents in, or are found or transact business in, this District.

26. This Court has personal jurisdiction over of the Defendants because, *inter alia*, each of the Defendants: (a) transacted business throughout the United States, including in this District; (b) marketed and sold infliximab throughout the United States, including in this District; (c) had substantial contacts with the United States, including in this District; and/or (d) engaged in an illegal conspiracy that was directed at and had the intended effect of causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

27. The activities of Defendants were within the flow of, were intended to, and did have, a substantial effect on interstate commerce of the United States. Defendants' products and services are sold in the flow of interstate commerce. The creation, marketing, sale and distribution of

Remicade and the actions complained of in this complaint, occur in and substantially affect interstate commerce.

CLASS ACTION ALLEGATIONS

28. Plaintiffs bring this action on behalf of themselves and as a class action under Rule 23(a) and (b)(2) of the Federal Rules of Civil Procedure, seeking equitable and injunctive relief on behalf of the following class (the "Injunctive Class"):

> All persons and entities in the United States and its territories, as defined herein, who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price of Defendants' infliximab from April 5, 2016 through the present ("Class Period"). This class excludes: (a) Defendants, their officers, directors, management, employees, subsidiaries and affiliates; (b) all federal and state governmental entities except for cities, towns or municipalities with self-funded prescription drug plans; (c) all persons or entities who purchased Defendants' infliximab for purposes of resale or directly from Defendants; (d) fully insured health plans (*i.e.*, health plans that purchased insurance covering 100% of their reimbursement obligation to members); (e) any "flat co-pay" consumers whose purchases of Defendants' infliximab were paid in part by a third-party payor and whose co-payment was the same regardless of the retail purchase price; (f) pharmacy benefit managers; and (g) any judges or justices involved in this action and any members of their immediate families.

29. Plaintiffs also bring this action on behalf of themselves and as a class action under Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure seeking damages on behalf of a nationwide class pursuant to state antitrust, unfair competition, and consumer protection laws detailed in Counts V-VII on behalf of the following class (the "State Damages Class"):

> All persons and entities in the United States and its territories, as defined herein, who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price of Defendants' infliximab from April 5, 2016 through the present ("Class Period"). This class excludes: (a) Defendants, their officers, directors, management, employees, subsidiaries and affiliates; (b) all federal and state governmental entities except for cities, towns or municipalities with self-funded prescription drug plans; (c) all persons or entities who purchased Defendants' infliximab for purposes of resale or directly from Defendants; (d) fully insured health plans (i.e., health plans that purchased insurance covering 100% of their reimbursement obligation to members); (e) any "flat co-pay" consumers whose purchases of Defendants' infliximab were paid in part by a third-party payor and whose co-payment was the same regardless of the retail purchase price; (f) pharmacy benefit managers; and (g) any judges or justices involved in this action and any members of their immediate families.

30. While Plaintiffs do not know the exact number of the members of the Classes, Plaintiffs believe there are at least thousands of members in each of the Classes.

31. Common question of law and fact exist as to all members of the Classes, thereby making relief appropriate with respect to the Classes as a whole. Questions of law and fact common to the Classes include, but are not limited to:

(a) Whether Defendants unlawfully excluded competition for biosimilar infliximab;

(b) The identity and participants in the scheme;

(c) The duration of the alleged scheme and the acts carried out by Defendants in furtherance of the suspect conduct;

(d) Whether the alleged conduct violated the Sherman Antitrust Act;

(e) Whether the alleged scheme violated various states antitrust and consumer protection statutes;

(f) Whether Defendants' conduct caused injury to the business or property of Plaintiffs and members of the Classes;

(g) Whether and to what extent Defendants concealed their wrongdoing;

(h) The effect of the alleged conspiracy on the prices of infliximab in the United States during the Class Period;

(i) The appropriate injunctive relief for the Classes; and

(j) The appropriate classwide measure of damages for the Classes.

32. Plaintiffs' claims arise out of the same common course of conduct giving rise to the claims of the other members of the Classes. Plaintiffs' interests are coincident with, and not antagonistic to, those of the other members of the Classes. Plaintiffs are represented by counsel who

are competent and experienced in the prosecution of antitrust, consumer protection and class action litigation.

33. The questions of law and fact common to the members of the Classes predominate over any questions affecting only individual members, including legal and factual issues relating to liability and damages.

34. Class action treatment is a superior method for the fair and efficient adjudication of the controversy, in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently and without the unnecessary duplication of evidence, effort and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress for claims that might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

35. The prosecution of separate actions by individual members of the Classes would create a risk of inconsistent or varying adjudications, establishing incompatible standards of conduct for Defendants.

FACTUAL ALLEGATIONS

Background

36. The Patient Protection and Affordable Care Act ("PPAC Act"), signed into law by President Obama on March 23, 2010, amends the Public Health Service Act ("PHS Act") to create an abbreviated approval pathway for biological products that are demonstrated to be "highly similar" (biosimilar) to or "interchangeable" with an FDA-approved biological product. These new statutory provisions also may be referred to as the Biologics Price Competition and Innovation Act of 2009 ("BPCIA").

37. The goal of the BPCIA is similar, in concept, to that of the Drug Price Competition and Patent Term Restoration Act of 1984 (a.k.a the "Hatch-Waxman Act") which created abbreviated pathways for the approval of generic drug products under Federal Food, Drug, and Cosmetic Act ("FFD&C Act"). The BPCIA aligns with the FDA's longstanding policy of permitting appropriate reliance on what is already known about a drug, thereby saving time and resources and avoiding unnecessary duplication of human or animal testing.

38. Under the BPCIA, a sponsor may seek approval of a "biosimilar" product under new §351(k) of the PHS Act. A biological product may be demonstrated to be "biosimilar" if data show that the product is "highly similar" to the reference product, notwithstanding minor differences in clinically inactive components, and that there are no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency.

39. In order to meet the higher standard of interchangeability, a sponsor must demonstrate that the biosimilar product can be expected to produce the same clinical result as the reference product in any given patient and, for a biological product that is administered more than once, that the risk of alternating or switching between use of the biosimilar product and the reference product is not greater than the risk of maintaining the patient on the reference product. Interchangeable products may be substituted for the reference product by a pharmacist without the intervention of the prescribing healthcare provider.

40. Inflectra and Renflexis are currently treated as "highly similar" or "biosimilar" to Remicade. Though it is reported that Pfizer is seeking to have Inflectra be considered "interchangeable" with Remicade for purposes of the BPCIA, any efforts to date have yet to bear fruit. Thus, while Inflectra is the equivalent of Remicade in terms of safety, purity and potency, before a patient can be moved from Remicade to Inflectra, Renflexis, or another competing biologic, a doctor must write a new prescription.

41. On February 4, 2014, FTC Commissioner and Chairwoman at the time Edith Ramirez noted the importance of free competition in the market for biologics and interchangeable biosimilars, how competition will bring down prices and expand access for sick Americans, and how Congress intended to facilitate this free competition once patent protection expires:

> As all of you know, biologic medicines are among the most important pharmaceuticals available today, providing life-saving therapies for difficult-to-treat diseases such as cancer, diabetes and multiple sclerosis. There are also among the most expensive, with costs often exceeding tens of thousands of dollars per year. Others have a price that is substantially higher and these costs may prevent some patients from accessing potentially life-saving therapies.
>
> Introducing competition into the biologics market place represents one of the most promising ways to reduce prices and expand access to these critical drugs.
>
> Most consumers are familiar with the cost savings associated with the introduction of generic drugs to compete with traditional brand name drugs. The abbreviated FDA approval process created by the Hatch-Waxman Act to introduce safe and effective generics has spurred price competition and expanded consumer access to many widely prescribed small molecule drugs.
>
> Recognizing the benefits of the Hatch-Waxman process, in 2010, Congress passed the Biologic Price Competition and Innovation Act, which created a statutory framework for follow-on biologic competition. This law required the FDA to develop an abbreviated approval pathway to promote competition for follow-on biologics, including both biosimilars and interchangeable biosimilars.
>
> While the FTC's 2009 Follow-On Biologics report found that a number of factors may result in different competitive dynamics and markets for follow-on biologics, it concluded that their introduction is likely to resulting in lower prices.

Federal Trade Commission ("FTC"), "Follow-On Biologics Workshop," at 8:15-9:24 (Feb. 4, 2014).

42. Insurance coverage and reimbursement are key to the adoption of a product because expensive drugs (like Remicade) will likely not be paid for out of pocket by patients. Most of the people who are prescribed Remicade have insurance or qualify for patient assistance. Because the drug is not one that can be picked up at a pharmacy, but is administered intravenously in a clinic or other institutional setting, it generally is not included under the "pharmacy benefit" of most health plans. In the pharmacy-benefit setting (in contrast to how infliximab is administered), physicians prescribe a drug and the patient procures the medication himself or herself at the pharmacy, paying

for it with a combination of insurance coverage (either private or government-sponsored) and out-of-pocket payment (usually a co-pay). In the pharmacy-benefit context, neither the prescribing physician nor the institution with which the physician is affiliated bears financial risk with respect to the drug selected, *i.e.*, the drug is not purchased and stocked in advance by providers at their own cost. The pharmacy buys the drug, dispenses it, and is reimbursed.

43. By contrast, products such as Remicade, sometimes referred to as "medical benefit" products, are administered at a clinic or other healthcare provider site, and the provider itself first purchases the drug product for use in the infusion treatment of patients and then later seeks reimbursement for the drug from a third-party payer (a practice commonly referred to as "buy and bill"). When a treatment is administered, the provider must secure payment for the service, including the cost of the product dispensed (which the provider had to pay up front with its own funds). In this context, the provider has a strong interest in utilizing drugs that are widely covered by insurance, particularly by the major national commercial health insurers and significant regional insurers active in its area.

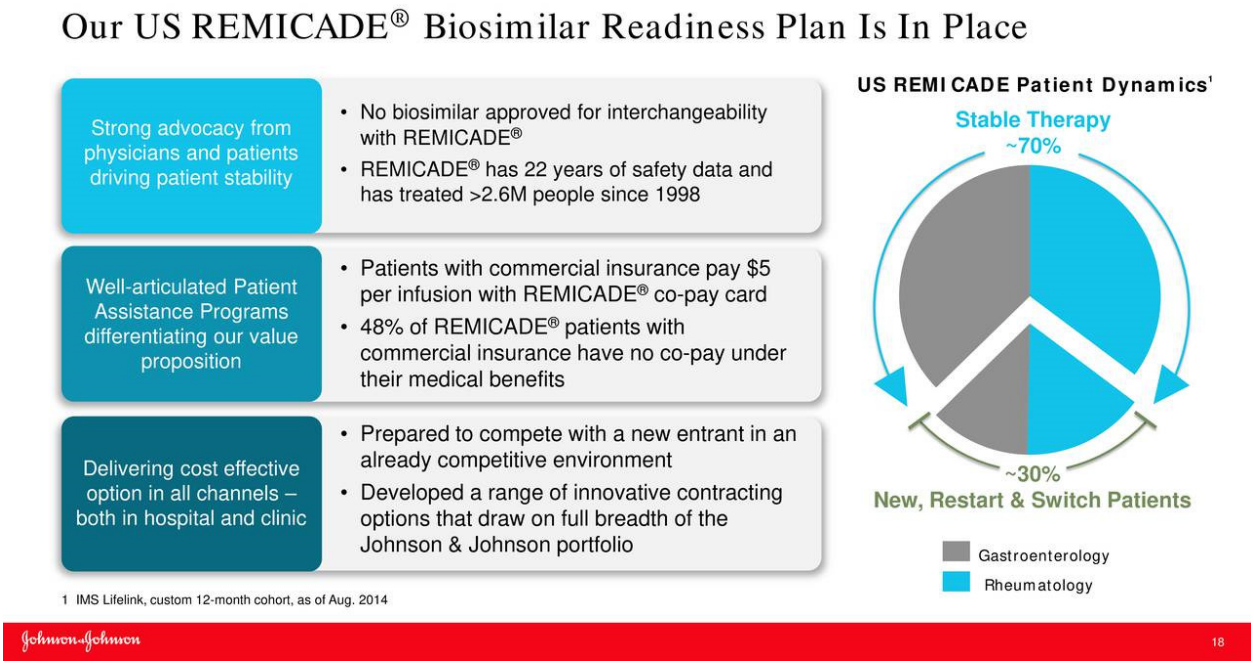
44. If a drug product is not widely covered, such that there is a risk that coverage might be denied, and providers thus would be burdened with a potential financial loss for what they paid for the product, providers are much less likely to purchase that product – a response that is in line with the providers' economic interests (to be reimbursed).

45. Commercial insurers typically publish medical policies enumerating the drug products they will cover under the medical benefit and the terms under which they will do so. For example, medical policies may exclude drugs from coverage, or they may dictate restrictions on use. Drug manufacturers compete, usually with rebates or other price concessions, to obtain coverage under insurer medical policies and to have either fewer restrictions on reimbursement than their competitors or, at a minimum, to achieve "parity," whereby the competing products have the same

restrictions on reimbursement and the patient and/or doctor can choose between them. Securing at least parity placement is critical, especially for new products seeking to gain traction in the marketplace, and particularly with large insurers, which have tens of millions of covered patients.

46. Part of J&J's exclusionary scheme was revealed in a conference call with analysts during which Joaquin Duato, worldwide chairman of J&J's pharmaceuticals group, said the company was gearing up for Pfizer's Remicade rival with a "focused biosimilar readiness plan." That plan includes trying to delay Pfizer's launch via an appeals process and sending out its sales reps to preach the superiority of Remicade's scientific track record and J&J's extensive patient-assistance program. J&J claimed that "70% of patients who are stable on Remicade are highly unlikely to switch."

47. The slideshow accompanying the J&J October 2016 earnings call stated: "Our US REMICADE® Biosimilar Readiness Plan Is In Place" and J&J is "[p]repared to compete with a new entrant in an already competitive environment [because J&J] [d]eveloped a range of innovative contracting options that draw on full breadth of the Johnson & Johnson portfolio." These supposed innovative options were part of the Company's anticompetitive scheme, which resulted in higher prices paid by Plaintiffs and the Classes. The below slide from J&J's third quarter 2016 earnings announcement details aspects of the Biosimilar Readiness Plan.



48. Analysts following J&J also noted the company's "plans to leverage innovative contracting strategies in all channels to fully compete with biosimilars." These so-called innovative strategies ensured that other competing entrants would be unable to grab a foothold in the market. Analysts were so sure that J&J's plan would work that they noted the company "should be able to navigate the threats from the biosimilar entry without any significant share loss in the next 12 months." This was the case even though both Samsung's and Pfizer's products were priced significantly below the J&J drug.

49. When asked about J&J's "defense strategy" for Remicade, Chief Executive Officer ("CEO") Alex Gorsky went so far as to say, "I would actually describe it as an offensive approach." A central feature of this "offensive strategy" entailed coerced exclusivity agreements with insurers.

50. As noted by an analyst at Sanford Bernstein: "Fancy footwork in J&J's U.S. marketing strategy made all the difference to the company's ability to hold on to market share." *See, e.g.*, Arelene Weintraub, *As Johnson & Johnson holds off U.S. biosims, Remicade's European market share falls to 50%*, FiercePharma (Dec. 5, 2017).

51. According to Pfizer, J&J has induced most major health insurers – covering at least 70 percent of commercially insured patients in the United States – to adopt contractual exclusivity restrictions and to impose outright bans on competing biosimilars' coverage, or so-called "fail first" requirements.

52. Pfizer alleges that some of the country's largest insurers, including Cigna and UnitedHealthcare, adopted "fail first" requirements, while Anthem excluded its product all together. Aetna has adopted a complex set of rules that operated in practice like the "fail first" requirements of Cigna and UnitedHealth. These health insurers cover tens of millions of Americans.

53. UnitedHealthcare's "fail-first" requirements are detailed in its Medical Benefit Drug Policy document. In that document, which is used to interpret UnitedHealthcare benefit plans (detailed below), the "fail-first" requirement shows that coverage of infliximab products other than Remicade only occurs if specific criteria are met. The criteria, that Remicade fail before a competitor is prescribed, however, makes little sense since it is doubtful that a prescriber would switch to another infliximab product if a patient was not showing improvement on the biosimilar Remicade.

This policy refers to the following infliximab products:
- Remicade® (infliximab)
- Inflectra™ (infliximab-dyyb)
- Renflexis™ (infliximab-abda)

Preferred Product:

Medical Necessity Plans

Remicade® (infliximab) is the preferred infliximab product. Coverage will be provided for Remicade® contingent on the coverage criteria in the *Diagnosis-Specific Criteria* section.

Coverage for Inflectra™ (infliximab-dyyb) or Renflexis™ (infliximab-abda) will be provided contingent on the criteria in this section and the coverage criteria in the *Diagnosis-Specific Criteria* section. In order to continue coverage, members already on Inflectra™ or Renflexis™ (infliximab-abda) will be required to change therapy to Remicade® unless they meet the criteria in this section.

Preferred Product Criteria

Treatment with Inflectra™ (infliximab-dyyb), Renflexis™ (infliximab-abda), or other infliximab biosimilar is medically necessary for the indications specified in this policy when BOTH the following criteria are met:

I. **One** of the following:
   A. **Both** of the following:
      1. History of a trial of at least 14 weeks of Remicade resulting in minimal clinical response to therapy and residual disease activity.
      2. Physician attests that. in their clinical opinion. the clinical response would be expected to be superior with Inflectra or other infliximab biosimilar product, than experienced with Remicade.

   or

   B. **Both** of the following:
      1. History of intolerance or adverse event to Remicade.
      2. Physician attests that. in their clinical opinion. the same intolerance or adverse event would not be expected to occur with Inflectra or other infliximab biosimilar product.

and

II. **Both** of the following
   A. Patient has **not** had a loss of a favorable response after established maintenance therapy with Remicade or other infliximab biosimilar product.
   B. Patient has **not** developed neutralizing antibodies to any infliximab biosimilar product that has lead to an attenuation of efficacy of therapy.[61]

54. Other regional insurers, like Blue Cross Blue Shield, have similar "fail first" requirements in place. Those entities similarly cover millions of patients.

Pfizer's Inflectra

55. After Inflectra's FDA approval in April 2016, and before J&J implemented its exclusionary contracts, Pfizer alleges that health insurers undertook reviews to determine whether there was a medical reason not to reimburse Inflectra or to disfavor it relative to other therapies. Following these reviews, several major health insurance companies – including at least Aetna, Anthem and UnitedHealthcare – classified Inflectra (like the FDA did) at parity with Remicade. By October 2016, UnitedHealthcare, the nation's largest health insurer, with over 30 million covered commercial medical patients, published an update to its medical and site of care policies classifying Inflectra at parity with Remicade for the approved indications (with an effective date of November 1, 2016). This meant that, for UnitedHealthcare, Inflectra would be reimbursed freely and would not be disfavored relative to Remicade. This confirmed that there was no medical reason justifying a restrictive reimbursement policy toward Inflectra. It also meant that, for the time being, Inflectra would be reimbursed without restriction. As a result, the stage was set for Inflectra to begin competing head-to-head with Remicade on a level playing field – and for purchasers to begin receiving the benefits of greater choice and lower prices.

56. These circumstances changed quickly, however, as just weeks later, according to Pfizer, UnitedHealthcare reversed course. Instead of being at parity, UnitedHealthcare classified Remicade as its "preferred" product and instructed that Inflectra would be eligible for reimbursement only in circumstances so limited as to be practically non-existent. Under UnitedHealthcare's new policy, Inflectra can be reimbursed only where the following conditions are met: (a) the patient must show a minimal clinical response, or an intolerance or adverse reaction, to Remicade; (b) the physician must attest that Inflectra would not lead to the same adverse responses; and (c) the patient

must show no loss of favorable response in established maintenance therapy with Remicade and must not have developed neutralizing antibodies to any infliximab biosimilar product that has made the therapy less effective. *See* image above, ¶53. As a practical matter, this meant that Inflectra, a drug the FDA approved as having no clinically meaningful differences in safety and efficacy, would not be reimbursed for UnitedHealthcare's more than 30 million commercial medical members, and that Remicade would be the exclusive infliximab with UnitedHealthcare. This despite the lack of any medical basis for denying those members access to a lower-priced alternative to Remicade. According to Pfizer, this change occurred after J&J induced UnitedHealthcare to enter into an exclusive deal by threatening to penalize UnitedHealthcare with the loss of significant rebates unless UnitedHealthcare agreed to deny coverage of Inflectra.

57. J&J has employed the same approach to secure exclusive deals with many other major insurers. In most cases these coercive biosimilar-exclusion contracts were the only economically viable option for insurers – as adopting any alternative would require the insurer to incur a substantial penalty (*i.e.*, foregoing rebates to existing Remicade patients) that could not be offset by the per-unit cost savings available on the number of patients likely to use the biosimilar, at least in the near term. Remicade is still on next year's list of preferred medicines at pharmacy-benefit managers Express Scripts Holding Co. and CVS Caremark, run by CVS Health Corp.[4]

58. In addition to the exclusive contracts, J&J also uses other means to maintain and enhance its monopoly. J&J is able to effectively leverage its large base of existing patients who are stabilized on Remicade. For the patients who are new patients who may be candidates for infliximab, Pfizer has focused, among other things, on competing for a substantial share of new patient starts – Pfizer calls these patients the "contestable" demand – by pricing Inflectra

[4] https://www.bloomberg.com/news/articles/2017-08-15/what-s-harder-than-making-copycat-biotech-drugs-selling-them.

competitively with both insurers and providers on a unit-for-unit basis. The fact that Inflectra's ASP is lower than Remicade's, and that Renflexis went to market at a price 35 percent below Remicade's, underscores the cost savings available. To counteract this, Pfizer alleges that J&J threatened to withhold attractive rebates on all Remicade prescriptions – including those for existing patients as well as new ones – unless an insurer agreed to exclusivity. This way J&J is able to leverage the incontestable demand for Remicade to exclude competition for the contestable demand, *i.e.*, it bundles the contestable and incontestable demand. Even if Pfizer offers a significantly lower price for Inflectra unit-for-unit, as it has done, insurers will agree to J&J's exclusive deals to avoid losing rebates on the substantial base of existing Remicade patients who are not likely to switch to Inflectra despite the presence of the lower-priced biosimilar. A recent article by two Yale Medical School professors in the *Journal of the American Medical Association* illustrates how the kind of leverage J&J has over existing stable Remicade patients allows it to extract commitments to exclude the biosimilar:

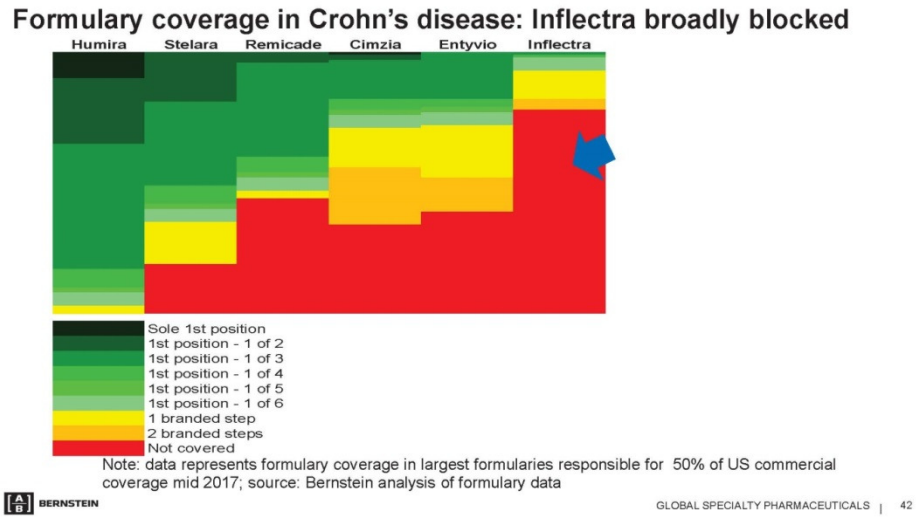
> If a biosimilar manufacturer intends to upend the preferred position of the brand by offering a substantial price discount to the [insurer], the branded manufacturer can respond by withdrawing the rebate on the [branded] biologic, creating a "rebate trap." For any patient continuing the [branded] biologic, a payer's cost for that patient will double once the rebate is withdrawn. . . . Even in [an] optimistic scenario, in which the price of the biosimilar is 60% less than the price of the brand after rebates and discounts, if the payer is only able to convert 50% of its patient users to the biosimilar [because existing patients will tend to stay on the original branded product], the rebate trap ensures that payer total costs actually increase relative to costs prior to biosimilar availability.
>
> To avoid the rebate trap, any strategy to reduce spending on biologics through adoption of biosimilars requires a near-complete switch of patient users from the branded biologic to the biosimilar. However, for many chronic diseases, the proportion of patients new to a given biological therapy is less than 20% of the total patients taking that drug in a given year. The remainder represents a stable base of patients whose disease is well-maintained while they are using current therapy and thus are unlikely to switch [to the biosimilar].[5]

[5] Aaron Hakim & Joseph S. Ross, *Obstacles to the Adoption of Biosimilars for Chronic Diseases*, Journal of the American Medical Association (May 1, 2017), http://jamanetwork.com/journals/jama/article-abstract/2625049.

59. J&J has further insulated its contracts with insurers from competition by bundling rebates for Remicade with rebates on other products in return for commitments not to cover Inflectra. As part of its "Biosimilar Readiness Plan," the company plans to leverage other products to ensure its monopoly. As J&J's Worldwide Chair for Pharmaceuticals said on a recent earnings call, "We are fully prepared to execute our focused biosimilar readiness plan," including "developing innovative contracts [to] utilize the full breadth of our portfolio." The "full breadth of [J&J's] portfolio" includes several drugs for which Pfizer does not offer any directly competing alternative. Pfizer alleges that J&J has threatened insurers with the loss of rebates on other drugs, as well as Remicade, if they do not agree to exclude Inflectra from coverage.

60. According to a presentation at a joint FTC/FDA meeting on drug competition by analysts at Bernstein, physician-administered drugs (like infliximab) have "two pressure points." One is that the physician must choose the product and the second is that the payer "can require preferring one product." As the analysts noted: "In the Remicade case, incumbent contracted exclusive position vs. the biosimilar with significant portion payers; thus every provider must stock innovator products." They also pointed out that J&J "then gave discounts to providers across a broad portfolio of products, conditioned on volume of Remicade (with an understanding of demand at each provider)."

61. Bernstein's analysis of formulary coverage (formularies are lists of drugs covered by insurers) in Crohn's disease, shows that Inflectra is broadly blocked compared to other drugs that treat the disorder, as the graphic below demonstrates:



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62. J&J's multi-product bundling, along with its bundling of contestable demand (*i.e.*, new patients) and incontestable demand (*i.e.*, existing Remicade patients), has amplified the anticompetitive effects of J&J's exclusive contracts and made the exclusivity provided by those contracts even more durable. Pfizer argues that insurers have made it clear to Pfizer that its net cost for Inflectra would need to be low enough to offset the loss of J&J rebates. But, because of the combined effect of these bundles, Pfizer cannot offset the financial penalties that J&J threatens to impose on insurers who do not agree to exclusivity. As a result, Pfizer is economically prohibited from competing for coverage by the major insurers – even when their exclusive contracts with J&J expire. J&J can use the same bundling strategies to ensure continuation of the exclusionary pattern.[6]

[6] In a Statement of Interest filed by the Department of Justice ("DOJ") on February 8, 2018, in *Marion Healthcare LLC v. Southern Illinois Healthcare*, No. 3:12-cv-00871-SCW, ECF No. 361 (S.D. Ill.) ("Statement"), the DOJ made clear, contrary to arguments made by J&J in its opposition and reply memorandum in support of the motion to dismiss the claims brought by Pfizer, that short-term exclusive contracts are not legal as a matter of law. Instead, the DOJ argued "exclusive contracts are evaluated under the rule of reason, and may be condemned if their 'practical effect' is to foreclose a substantial portion of the market to competition. *Tampa Elec. Co. v. Nashville Coal Co.*, 365 U.S. 320, 326-28 (1961); Statement at 3.

63. "Access for Inflectra has been substantially limited due to J&J's pursuit of exclusionary contracting with insurers and providers. Our lower-priced product has not received access at parity to Remicade and remains in a disadvantaged position despite recent price increases of Remicade," Pfizer said in a statement.[7]

64. Providers are unwilling to stock a drug product where there is significant uncertainty about whether it will be reimbursed by health insurers; and, because they administer infliximab onsite, providers must expend funds for the product in the first instance, then seek reimbursement after providing treatment. The provider has theoretical recourse against the patient where coverage is denied, but the prospect of securing payment in full from the patient is bleak, especially for drugs as costly as Remicade. As a result, where a significant portion of a provider's patients are insured by plans that have agreed to exclude Inflectra or Renflexis – pursuant to the types of contracts described above – the provider is unlikely to offer the competing products to any of its patients to avoid being caught with no reimbursement.

65. Similarly, J&J sought to influence patients' decision-making by creating disincentives for patients to switch. As a recent article explained:

> [P]atients who hope to achieve cost savings by switching from the reference infliximab to a biosimilar treatment may face disincentives from their health plans. UnitedHealthcare, for example, continues to prefer Remicade to biosimilar treatments, and noted in its July bulletin that patients who want to switch to the biosimilar Renflexis may be required to transition their infusion services to another site of service if they want to continue to receive coverage.[8]

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[7] https://www.bloomberg.com/news/articles/2017-08-15/what-s-harder-than-making-copycat-biotech-drugs-selling-them.

[8] Kelly Davio, *When Will Patients Benefit from Deepening Infliximab Discounts?*, The Center for Biosimilars (Sept. 5, 2017), http://www.centerforbiosimilars.com/news/when-will-patientsbenefit-from-deepening-infliximab-discounts.

This tactic was first applied to Inflectra and subsequently to Renflexis.[9]

66. *Bloomberg* has reported on the issue, noting that Ascension Health, a nearly 23,000-bed nonprofit hospital system based in St. Louis, spends $55 million a year on J&J's Remicade, more than any other drug. "Using Inflectra, part of a new class of medicines called biosimilars, would save it at least $10 million annually, according to Ascension's chief pharmacist, Roy Guharoy." The article notes that the pharmacist planned to integrate Inflectra into care more often until learning that insurers preferred to stay with Remicade. "This we did not expect," Guharoy said. "If the insurance companies force us to use the branded product, of course our hands are tied."

67. USB Global Research noted the same constraints, stating that "contracting and coverage will play a greater role in driving choice of therapy than the preferences of physicians or patients."

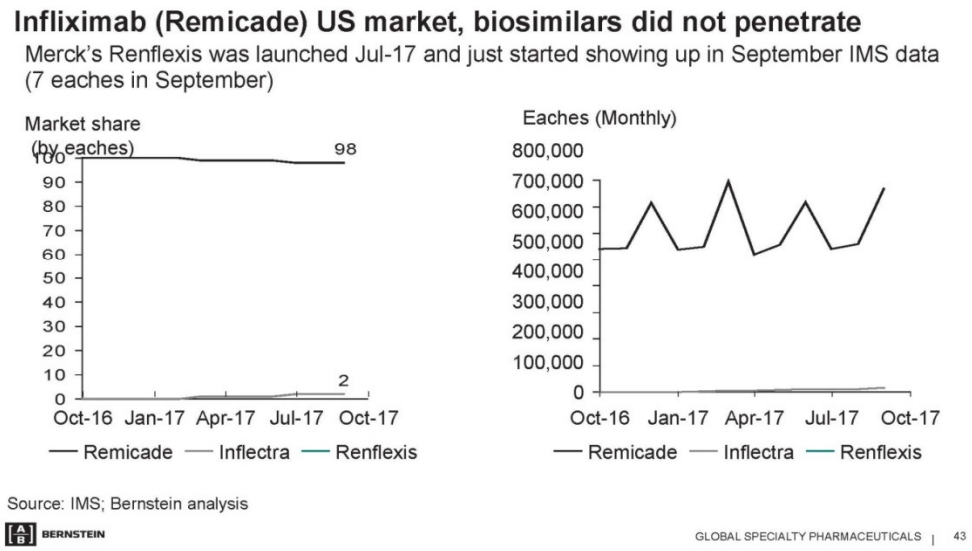
68. J&J touts the excluded status of Inflectra in its marketing communications, knowing that doing so will discourage providers from stocking the new biosimilar. J&J markets the "fail first" requirement as a selling point despite the fact that such a provision is medically inappropriate and despite the FDA's determination that there are no clinically meaningful differences between the two products. J&J touts Remicade as "Preferred Over Inflectra . . . Inflectra requires trial and failure on Remicade prior to [Inflectra] utilization."

69. Given the widespread gaps in Inflectra's insurance coverage – caused by J&J – providers using infliximab have overwhelmingly chosen to stock only Remicade (which is essentially universally covered given its long tenure and dominant position) rather than deal with the risk of possible denials of coverage for Inflectra. Thus, providers have declined to purchase Inflectra across the board, even for patients covered by commercial or government insurance plans that do

[9] *See* United Healthcare Network Bulletin, at 6 (July 2017), https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/News/July-Interactive-Network-Bulletin-2017.pdf.

cover the product. The effective foreclosure of biosimilars, as a direct result of J&J's anticompetitive contracts, thereby is expanded well beyond the 70 percent of commercially insured patients directly foreclosed by J&J's insurer contracts. Indeed, as of September 1, 2017, about 90 percent of healthcare provider accounts using infliximab had purchased no Inflectra at all.

70. The below chart demonstrates the limited market share of competitors to Remicade.[10]



71. In addition to its exclusionary, competition killing contracts with insurers, J&J has imposed exclusionary contracts on providers themselves (*e.g.*, clinics, hospitals, etc.). After Pfizer introduced Inflectra, J&J began offering certain large providers additional rebates and/or discounts on Remicade, but only if the provider committed to buy Remicade for nearly all of its infliximab needs. To be eligible for rebates, J&J required providers to maintain purchase levels for Remicade very close to the levels of the year before Inflectra's launch – when Remicade was the only

[10] IMS Health is a leading provider of detailed health data. IMS can measure as either prescriptions written and filled (30 day, 60 day, and 90 day), units sold (both in terms of bottles or packages), or "eaches" (the number of individual pills, tablets or capsules or injections delivered).

infliximab option. With about 30 percent of prescriptions in any year representing new patients (and a certain percentage of existing patients exiting therapy each year), this condition also requires providers to use Remicade for new patients if they wish to secure payment from J&J, thus bundling contestable and incontestable demand for Remicade. Like its insurer-level contracts, these contracts as a practical matter make Remicade the exclusive infliximab with the participating providers.

72. Multi-product bundling is also used by J&J in its provider-level contracts. As one analyst reported, "J&J bundled several drugs and medical devices for larger hospitals, making Inflectra less economical." Conditioning rebates linked to other J&J products upon a promise not to do business with Inflectra only exacerbates the exclusionary nature of J&J's contracts.

73. Meanwhile, Pfizer argues that it is prepared to negotiate with providers to make Inflectra the lower-priced infliximab option on a per-unit basis, and has even offered to guarantee that Inflectra would be less expensive unit-for-unit than Remicade. But as with insurer contracts, to secure the right to deal freely as to Inflectra (*i.e.*, principally as to new patients), the providers would lose significant J&J rebates on their existing Remicade patient bases.

Samsung's Renflexis

74. Samsung and Merck received FDA approval for their Remicade biosimilar, Renflexis, on April 21, 2017. Like Inflectra, Renflexis was approved for all eligible indications, including Crohn's Disease, pediatric Crohn's Disease, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and plaque psoriasis.

75. Just a month later, on May 17, 2017, Janssen filed suit against Samsung alleging that Renflexis violated three of its manufacturing process patents. Samsung responded that "[w]e are confident we do not infringe Janssen's patents," and further stated its belief that the suit was filed to delay entry of Renflexis. Samsung said it would "take all necessary measures against Janssen's attempts to violate patient rights and deny patient access to effective, lower cost treatment options."

76. According to Samsung: "When the lawsuit was filed, Samsung . . . was convinced that it did not infringe any patents and started to sell Renflexis in the US from July, because it believes that the originator firm is trying to postpone the entry of biosimilars in the market."

77. Analysts agreed, noting that biotech makers face increasing competition from firms such as Samsung, which make biosimilar copies of Remicade and other drugs and sell them cheaper. The IMS Institute for Healthcare Informatics reported that biosimilars could save healthcare systems in the United States and Europe's top five markets more than $108 billion by 2020.

78. Janssen abruptly dropped its patent case against Samsung in November 2017, filing a notice of voluntary dismissal with prejudice with the U.S. District Court in New Jersey. Samsung officials noted that "Janssen's withdrawal of the lawsuit marks a positive step towards improving patient access to biosimilars in the United States."

79. As with Pfizer's biologic, Samsung began selling Renflexis in July 2017 at a price 35 percent less than the list price of Remicade.

80. The dismissal of most of its claims, along with the invalidation of a central Remicade patent at issue in the patent litigation, suggests that Janssen's lawsuit lacked a legitimate basis and constituted sham patent litigation intended to impermissibly forestall competition to Remicade.

J&J Has Made It Impossible to Compete

81. Experts in the field have noted that an "unusual convergence of market factors" have made Inflectra and Renflexis less than the blockbusters that had been anticipated. According to a review in *Managed Care Magazine* by Nicolle Rychlick, director of clinical integration and implementation at HealthTrust, "Instead of taking the market by storm, they have made little headway against Remicade and its hegemony as the biologic for 1.3 million Americans with rheumatoid arthritis."

82. Rychlick noted that winning over payers has been "an uphill battle." This is "in part because most commercial payers receive rebates from Johnson & Johnson on Remicade, so it has maintained its preferred spot on many formularies." Pricing differences have not been enough. As Rychlick explained: "Pfizer brought Inflectra to market in 2016 priced 19% below Remicade [and, Merck] did Pfizer one better by pricing Renflexis 15% lower than Inflectra. . . . [T]he rebate deals Johnson & Johnson is privately striking with insurers are apparently enticing enough in the aggregate to give Remicade most-favored status – at least for now."

83. In order to compete, Pfizer's marketing partner Celltrion is considering an even steeper discount than the price cut it had at launch. According to an article in the *Korea Herald* from January 12, 2018, Celltrion CEO Seo Jung-jin said during a session at JP Morgan Healthcare Conference in the United States that "[w]e are discussing ways to price Inflectra at a 50 percent discount over the original drug with our marketing partner Pfizer. We believe that this may be possible by cutting manufacturing costs and distribution margins." The discount strategy comes as Inflectra still has a less than 2 percent market share, although Pfizer released it in late 2016 at a 15 percent discount over Remicade's price. Later, the price gap widened to 19 percent.

84. This case, in many ways, is a case of first impression for the biosimilar industry and is important to uphold not only the plain statutory language of the BPCIA, but also Congress's intent in the law's passage. *See* [Proposed] Brief of the Biosimilars Council As *Amicus Curiae* in Opposition to Defendants' Motion to Dismiss, *Pfizer, Inc. v Johnson & Johnson and Janssen Biotech, Inc.*, No. 2:17-cv-04180-JCJ, Pfizer ECF No. 45-1 (E.D. Pa. Jan. 26, 2018) ("Amicus Brief), https://www.accessiblemeds.org/sites/default/files/2018-01/AAM-Amicus-Brief-Pfizer-vs-J%26J-1-26-18.pdf.

85. The Biosimilars Council, a division of the Association for Accessible Medicines ("AAM"), has weighed in on J&J's actions with infliximab. AAM is the non-profit voluntary trade

association representing companies that develop and manufacture generic and biosimilar medicines reviewed and approved by the FDA that has sought to file an amicus curiae brief in opposition to J&J's motion to dismiss is *Pfizer*'s action. This group represents nearly 100 manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical ingredients, and suppliers of other goods and services to the generic pharmaceutical industry. Neither Pfizer nor J&J are members of the Biosimilars Council.

86. The Biosimilars Council identified five key points demonstrating the significance of this litigation: (1) that there is need for competition in the market for biologics; (2) that Congress sought to facilitate price competition through the BPCIA; (3) biosimilars have the potential to produce savings and increase patient access; (4) biosimilars are costly to develop and market; and (5) the market for biosimilars is in its infancy, and incentives to produce biosimilars must be protected and reinforced. *See* Amicus Brief; *see generally* http://www.centerforbiosimilars.com/news/biosimilars-council-backs-pfizer-with-amicus-brief-in-ongoing-infliximab-case.

87. The Biosimilars Council contends that the case between Pfizer and J&J presents critical issues regarding the degree to which biosimilars will "be allowed to compete on fair terms with higher-priced branded biologic medicines, as Congress intended when it enacted the BPCIA." Amicus Brief at 2.

88. The Biosimilars Council, in noting that Inflectra is one of only a few biosimilars that have been approved by the BPCIA, argues that as more biosimilars are approved, "exclusionary tactics such as those used by Defendants to prevent Inflectra from competing against Defendants' branded infliximab product Remicade®, if upheld, will provide a roadmap for other pharmaceutical companies to stifle biosimilar competition." *Id.* at 2. Moreover, "[r]eplication of these tactics across biologics markets will dramatically diminish incentives for developing future biosimilars, and competition in this critical, growing sector of the health care industry will suffer." *Id*

89. AAM notes that biosimilars have begun to gain momentum following the FDA's issuance of important guidance related to the BPCIA. Many biosimilar approvals are on the horizon, but "[m]aintaining this momentum, however, depends on preserving fair, unfettered price competition in biologics markets." As they report, "If brand name drug companies are able to prevent competition by unfairly blocking market access or discouraging insurers' and providers' use and reimbursement of approved biosimilars, biosimilar manufacturers will fail to capture the market share that befits FDA's finding of clinical similarity (or interchangeability). Failure to capture adequate market share will thus dramatically reduce biosimilar manufacturers' incentives to undertake the costly, time-consuming processes of biosimilar development and marketing." *Id*. at 10. By extension, the harms outlined not only affect Plaintiffs and the proposed Classes here, but also could potentially affect millions of Americans that may in the future benefit from a new biologic that has yet to be invented.

90. It is critical, the AAM's Biosimilars Council contends, "at this early stage of the biosimilars industry that the incentives for biosimilar development and marketing be protected and reinforced, and that brand name drug companies be prevented from using exclusionary tactics that stifle fair price competition in the marketplace and, ultimately, harm patients and consumers nationally." *Id.* at 11.

91. J&J's "Biosimilars Readiness Plan," which is a multi-part scheme to maintain control of its lucrative market position through a web of conduct, if left unchecked "could serve as a blueprint for every brand name biologic drug maker seeking to maintain monopoly power and profits indefinitely in the face of competition from a lower-priced biosimilar." *Id*. at 12.

92. The exact problem that was the goal of the BPCIA to remedy is undermined by J&J's scheme. "J&J's strategy to block competition from an approved biosimilar rests on and exploits the

longstanding monopoly advantages that Congress sought to remedy through the BPCIA's expedited biosimilar approval pathway." *Id*. at 14.

93. The pharmaceutical companies, seeing opportunity to foreclose the competition that Congress envisioned by passing the BPCIA, which allows for doctors and patients expanded access to cheaper biosimilar alternatives, have been lobbying state legislatures across the country with the intent to make it harder for patients to use FDA-approved biosimilars. In 2013 alone, at least 15 states considered bills concerning follow-on biologics. *See* FTC, "Follow-On Biologics Workshop," Feb. 4, 2014 at 11:2-11:3. Many of these laws were designed by pharmaceutical companies with the intent to make access to these important medicines more difficult. *Id*. at 11:4-12:22.

J&J's Conduct in the Patent Arena Is Anticompetitive

94. In 2014, prior to Pfizer's entry into the market, Celltrion (later acquired by Pfizer) sought a declaratory judgment in Massachusetts regarding Janssen's "manipulative and deceptive practices before the U.S. Patent & Trademark Office to improperly extend the length of its patent monopoly for Remicade and to obtain patents the Patent Office never would have issued had it known all material facts." Celltrion's Complaint for Declaratory Judgment, at 3 (D. Mass. Mar. 31, 2014).

95. That complaint charged that Janssen "employed a variety of manipulative legal and other tactics to aggressively extend its multi-billion dollar patent over Remicade throughout the world." *Id*.

96. Celltrion brought the case prior to receiving FDA approval to head off later and expected challenges from Janssen. As Celltrion explained, "Because Celltrion expects to face patent infringement allegations from Janssen, Celltrion wants to start the adjudicative process regarding the invalidity and unenforceability of Janssen's patents. This will enable Celltrion to immediately avail itself of the processes available in the federal judiciary to discover information relating to Janssen's

patents, to learn Janssen's claim constructions and infringement contentions, and to present issues speedily for adjudication and test the validity and enforceability of Janssen's patents." *Id*. at 4.

97. Three patents purportedly cover Remicade ('396, '452 and '471). Celltrion's complaint for declaratory judgment alleged that Janssen acted improperly in regard to Remicade patents in a wrongful attempt to extend its grip on the multi-billion dollar market for Remicade. The wrongful conduct included a purposeful delay in the prosecution of the '471 patent, extending more than seven years. "The '471 applicants' unexplained and unreasonable delays in prosecuting the '471 application resulted in a significant delay in patent issuance, and thus a later expiration date." *Id*. at 15.

98. As to the '396 patent, Janssen "breached its duty of candor and engaged in inequitable conduct before the Patent Office to obtain its '396 patent." *Id*. at 15.

99. Celltrion further charged Janssen with taking aggressive and questionable actions worldwide to try to protect its monopoly. In addition to the filing of a number of patent infringement suits in the United States, Janssen tried to "disrupt and delay" the introduction of competition in countries around the world, including in Canada, the United Kingdom, Mexico and other large markets.

100. The complaint also claims that J&J submitted a Citizen's Petition. "In the United States, on January 7, 2014, Johnson & Johnson submitted a Citizen's Petition asking the FDA 'to require biosimilars to bear nonproprietary names that are similar to, but not the same as, those of their reference products or of other biosimilars.' In its petition, Johnson & Johnson specifically mentions Remicade® as one of the biologic drugs in its biologics portfolio. Johnson & Johnson

argues that nonproprietary names of biosimilars should differ in order to simplify safety monitoring post-approval and to avoid confusion among pharmacists, doctors, and patients."[11]

101. This frivolous argument has been made time and again by pharmaceutical companies and has been rejected by industry experts, courts and even legislatures who have been faced with bills containing similar provisions. Indeed, having similar names is important and furthers the purpose of the BPCIA. Aaron Kesselheim, Associate Professor of Medicine at Harvard Medical School, in noting that "the name is actually critical," said (in the context of generics and the Hatch-Waxman Act) that "the similar namings of the small molecule and brand name products were key to the implementation of the Hatch-Waxman Act." *See* FTC, "Follow-On Biologics Workshop," at 34:2-7 (Feb. 4, 2014). This is because of the pharmaceutical companies' relentless marketing, as "the public is skeptical about things labeled generic. And generic biologic drugs will have to compete by providing a substantial investment into marketing against the brand name products if there isn't this sort of [drug name] interchangeability that's allow[ed now]." *Id.* at 34:10-14.

102. On March 6, 2015, Janssen filed a lawsuit against Celltrion and Hospira, Inc. (subsequently acquired by Pfizer), alleging patent infringement. On August 17, 2016, J&J's patent covering the infliximab antibody was ruled invalid by the U.S. District Court for the District of Massachusetts, a ruling that confirmed that J&J had no valid right to exclude Pfizer or other potential entrants. In the district court ruling, the court held the antibodies covered by J&J's Remicade patent had been disclosed and claimed in an earlier patent.

103. Following the Massachusetts decision, the U.S. Patent and Trial Appeal Board (of the U.S. Patent and Trademark Office) issued a final decision in a re-examination of the same patent,

[11] Often filed on or near the eve of generic entry, Citizen Petitions can have the effect of delaying final Abbreviated New Drug Application approval while the FDA sifts through and evaluates if the petitioners' arguments have merit.

holding that the patent was invalid. That decision was appealed, and on January 23, 2018, the U.S. Court of Appeals Court for the Federal Circuit affirmed the decision.

104. In another action on May 17, 2017, Janssen filed suit against Samsung alleging that Renflexis violates three of its manufacturing process patents. Samsung responded that "[w]e are confident we do not infringe Janssen's patents," and further stated its belief that the suit was filed to delay entry of Renflexis.

105. Notably, by the time Janssen filed its lawsuit against Samsung, Janssen had already stipulated to the dismissal of its claims against Celltrion and Hospira for infringement of the '600 patent and the '056 patent; in addition, within weeks of filing its lawsuit against Samsung, Janssen subsequently stipulated to the dismissal of its infringement claims against Celltrion and Hospira regarding the '083 patent.

106. The voluntary dismissal of most of its patent infringement claims, along with the invalidation of a central Remicade patent at issue in the patent litigation, suggests that Janssen's lawsuits against the above-referenced biosimilar manufacturers lacked a legitimate basis and constituted sham patent litigation intended to impermissibly forestall competition to Remicade.

J&J POSSESSES MONOPOLY POWER IN THE RELEVANT PRODUCT MARKET

107. Monopoly power is the ability of a single seller to raise prices above the competitive price level without losing significant business.

108. At all relevant times, J&J had monopoly power in a market limited to infliximab and was able to control prices and exclude relevant competitors.

109. At all relevant times, J&J had monopoly power in a market limited to infliximab because it had the power to raise or maintain the price of Remicade at supracompetitive prices without losing enough sales to make supracompetitive prices unprofitable. For years before Inflectra's entry, J&J's ASP for Remicade increased, yet Remicade did not lose business. Between

2007 and 2017, Remicade's ASP increased more than 62 percent. Despite Remicade's price hikes, unit sales of Remicade have actually grown 15 percent during the period from 2012 to 2016.

110. The introduction of Pfizer's competing product has not eroded Remicade's monopoly power. Instead, since Inflectra was launched, Remicade's ASP has increased without affecting its market position. Ten months after Inflectra's introduction, Remicade still accounted for more than 96 percent of all infliximab sales. Even as Remicade saw a slight erosion in sales in its fourth quarter 2017 results due to some price declines, the company touted that the drug had maintained well over 90 percent of its market share, and that it saw "far less of an impact in 2017 than expected."

111. Pfizer's Inflectra sales demonstrate its struggles – the medication turned in just $74 million in the United States through the first nine months of 2017. Remicade, on the other hand, generated $4.5 billion in U.S. sales last year, J&J reported on January 23, 2018. J&J's investor relations V.P. Joseph Wolk said Remicade's volume is still up "around the high 90%." Remicade remained J&J's biggest selling drug in 2017, generating $6.3 billion in sales around the globe.

112. Infliximab is an infusion-administered TNF-inhibiting immunosuppressant with FDA-approved indications for rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, ulcerative colitis, Crohn's disease, and plaque psoriasis (together, the "Relevant Indications").

113. The relevant product market is the market for biologic infliximab (the "Relevant Product Market"). Because of the heightened effectiveness of the biologic compared to its biologic competitors and prescription drug analogs, which treat the Relevant Indications, those competitors and analogs are not substitutes. The pricing of the biologic bears this out: despite increased prices for Remicade, substitution has not occurred and its sales have not declined. Remicade has over a 90 percent share of this market.

114. Alternatively, the broadest possible relevant product market is infusion-administered drugs whose approved labeling from the FDA: (a) encompasses one or more of the Relevant Indications, and (b) is without restriction for the applicable Relevant Indication, that is to say, the labeling does not specify that the drug may be used for the applicable Relevant Indication only after the patient has not responded to another therapy. Remicade enjoys a share of over 60 percent in the Relevant Product Market, nearly the same share it had before Inflectra entered.

115. Certain non-infusion drugs are also indicated to treat the Relevant Indications. None of those drugs, however, is a reasonable substitute for the infusion-administered products. None significantly constrains the prices J&J is able to charge for Remicade.

116. The non-infusion products approved for the Relevant Indications include oral medications (*e.g.*, Xeljanz) and self-injectables (*e.g.*, Humira, Enbrel). These products are patient-administered. Infusion drugs, by contrast, must be delivered by healthcare professionals in a clinical setting (*e.g.*, hospitals or infusion centers) during infusion sessions that take upwards of two hours.

117. Functional similarities between Remicade and non-infliximab products are insufficient to permit inclusion of those other products in the Relevant Product Market with Remicade. To be an economic substitute for antitrust purposes, a functionally similar product must exert sufficient pressure on the prices and sales of another product so that the price of that other product cannot be maintained at supracompetitive levels. No other products apart from biosimilar versions of Remicade could have taken away sufficient sales from Remicade and/or prevented J&J from raising or maintaining the price of Remicade at supracompetitive levels. Absent the conduct challenged in this case, only biosimilar versions of Remicade would have presented J&J with the choice of lowering price or losing unit sales.

118. A small but significant non-transitory price increase in the price of Remicade did not cause, and would not cause, a significant loss of Remicade unit sales to drugs other than infliximab

products. Remicade does not exhibit significant, positive cross-elasticity of demand with respect to any non-infliximab formulations or treatments and, absent the challenged conduct, would only exhibit such elasticity of demand with biosimilar versions of infliximab.

119. Physicians are not likely to switch from prescribing their patients infliximab to prescribing those non-infusion products in response to a small but significant non-transitory change in the price of infliximab.

Barriers to Entry

120. Substantial barriers to entry exist to developing other infusion-administered drug therapies for the Relevant Indications generally, and infusion-administered TNF-inhibitors specifically. The development of a new therapy requires tens if not hundreds of millions of dollars and substantial risk, as any new product must survive years of research and development, clinical trials, and FDA approval. If left unchecked, J&J's conduct will serve as an additional barrier to entry, as potential new entrants will recognize that they will be unable to break J&J's "rebate trap" and thus to profitably enter the Relevant Product Market – and consequently will not invest the resources necessary to develop biosimilars.

Geographic Market

121. The relevant geographic market for the Relevant Product Market alleged herein is the United States of America and its possessions and territories, as these products are marketed and sold on a national basis.

J&J's Conduct Has Stifled Competition in the Relevant Product Market

122. The acts and practices detailed above have caused substantial harm to the competitive process as well as to purchasers, who have been deprived of the principal benefits of competition – more choices and lower prices. The anticompetitive effects of J&J's conduct are evident in its pricing of Remicade since Inflectra's (and more recently Renflexis's) entry into the market. Despite

the fact that Pfizer has offered substantial discounts and a lower ASP to compete for business with insurers and healthcare providers, J&J has been able to increase the price of Remicade without losing any significant share or volume of sales to Pfizer (or any other competitor). J&J's prices for Remicade have been increasing by every measure. J&J has increased Remicade list prices twice since FDA approval of Inflectra. These increases alone raised Remicade's list price nearly 9 percent.

123. There is no efficiency or cost-reducing justification for J&J's coercive and exclusionary insurer- or provider-level contract terms. J&J has not achieved improved production costs, or economies of scale or scope through its contracting strategies. J&J also has achieved no improvements in the Remicade treatment through its contracting strategies. The intent and effect of J&J's conduct was to maintain and strengthen its monopoly position for infliximab.

Effects on Interstate Commerce

124. Defendants' conduct in unlawfully monopolizing and restraining trade and competition in the market for infliximab has substantially affected interstate and foreign commerce.

125. During the relevant time period, Defendants manufactured, promoted, distributed and sold substantial amounts of infliximab in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

126. During the relevant time period, Defendants transmitted funds as well as contracts, invoices and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of infliximab.

127. In furtherance of their successful efforts to monopolize and restrain competition in the market for infliximab, Defendants employed the U.S. mail and interstate and international telephone lines, as well as means of interstate and international travel. The activities of Defendants were within the flow of and have substantially affected interstate commerce

Effect on Intrastate Commerce

128. During the relevant time period, infliximab, manufactured and sold by Defendants, was shipped into each state and was sold to or paid for by Plaintiffs.

129. During the relevant time period, in connection with the purchase and sale of infliximab, money exchanged hands and business communications and transactions occurred in each state.

130. Defendants' conduct as set forth in this complaint had substantial effects on intrastate commerce in that, *inter alia*, sellers of infliximab within each state were foreclosed from offering cheaper infliximab to Plaintiffs purchasing inside each respective state that affected commerce in each state.

Antitrust Impact

131. During the relevant period, Plaintiffs and members of the Classes purchased substantial amounts of infliximab indirectly from Defendants and/or purchased substantial amounts of infliximab indirectly from Defendants and others. As a result of Defendants' illegal conduct, members of the Classes were compelled to pay, and did pay, artificially inflated prices for their infliximab requirements. Those prices were substantially greater than the prices that members of the Classes would have paid absent the illegal conduct alleged herein, because: (1) the price of Remicade was artificially inflated by Defendants' illegal conduct; and (2) Class members were deprived of the opportunity to purchase other biosimilar products. The supracompetitive prices were paid either at the point of service, in the Plaintiffs' participants' home state or the Plaintiffs' headquarters.

132. As a consequence, Plaintiffs and members of the Classes have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial. Commonly used and well-accepted economic models can be used to measure both the extent and the

amount of the supracompetitive charges passed through the chain of distribution to Plaintiffs and members of the Classes.

133. General economic theory recognizes that any overcharge at a higher level of distribution generally results in higher prices at every level below. *See* Prof. Herbert Hovenkamp, *Federal Antitrust Policy, The Law of Competition and Its Practice* at 624 (1994). According to Professor Hovenkamp, "[e]very person at every stage in the chain will be poorer as a result of the monopoly price at the top." Professor Hovenkamp also acknowledges that "[t]heoretically, one can calculate the percentage of any overcharge that a firm at one distribution level will pass on to those at the next level."

134. Further, the institutional structure of pricing and regulation in the pharmaceutical drug industry, and specifically the pricing of infusion-administered biologics, assures that overcharges at the higher level of distribution are passed on to Plaintiffs and the Classes.

135. Defendants' anticompetitive actions enabled them to indirectly charge Plaintiffs in excess of what they otherwise would have been able to charge absent their unlawful actions.

136. The prices were inflated as a direct and foreseeable result of Defendants' anticompetitive conduct.

137. The inflated prices the Classes paid are traceable to, and the foreseeable result of, the overcharges by Defendants.

COUNT I

Violation of §2 of the Sherman Antitrust Act, 15 U.S.C. §2
(Monopolization of the Relevant Product Market)
(On Behalf of the Injunctive Class)

138. Plaintiffs repeat and reallege each of the foregoing paragraphs of this complaint and incorporate them by reference as though set forth in full herein.

139. J&J has monopolized the Relevant Product Market in violation of §2 of the Sherman Antitrust Act ("Sherman Act").

140. Through the scheme described above, and other conduct likely to be revealed in discovery, J&J has willfully and unlawfully maintained and enhanced its monopoly power in violation of §2 of the Sherman Act. J&J's scheme constitutes unlawful exclusionary conduct within the meaning of §2 of the Sherman Act.

141. J&J's scheme has stifled competition in the Relevant Product Market and thwarted Congress's purpose in enacting the BPCIA.

142. Among other things, given that: (a) J&J imposed explicit conditions that insurers and providers eliminate (or almost completely curtail) their dealings with infliximab biosimilars, and (b) J&J's ASP for Remicade has actually increased since biosimilars entered the market, J&J's pricing is not the clearly predominant means by which competition has been foreclosed in the Relevant Product Market.

143. Even if price were deemed to be the clearly predominant means by which competition has been foreclosed, when the total amount of discounts and rebates that J&J offers to insurers and providers under the contracts described herein, including multi-product bundled contracts, is attributed to the portion of Remicade sales that is contestable by a biosimilar like Inflectra, J&J is pricing Remicade below its own average variable cost.

144. As a result of J&J's conduct, and the harm to competition caused by that conduct, Plaintiffs and the Classes have suffered substantial and continuing injuries.

COUNT II

Violation of §2 of the Sherman Antitrust Act, 15 U.S.C. §2 (Attempted Monopolization of the Relevant Product Market) (On Behalf of the Injunctive Class)

145. Plaintiffs repeat and reallege each of the foregoing paragraphs of this complaint and incorporate them by reference as though set forth in full herein.

146. J&J has attempted to monopolize the Relevant Product Market in violation of §2 of the Sherman Act, 15 U.S.C. §2.

147. J&J is violating §2 of the Sherman Act by attempting to implement the anticompetitive scheme set forth above with the specific intent to monopolize the Relevant Product Market. J&J's scheme constitutes exclusionary conduct within the meaning of §2 of the Sherman Act.

148. There is a dangerous probability that J&J will succeed in monopolizing the Relevant Product Market through its anticompetitive scheme.

149. J&J's scheme has stifled competition in the Relevant Product Market and thwarted Congress's purpose in enacting the BPCIA.

150. Among other things, given that: (a) J&J imposed explicit conditions that insurers and providers eliminate (or almost completely curtail) their dealings with infliximab biosimilars, and (b) J&J's ASP for Remicade has actually increased since biosimilars entered the market, J&J's pricing is not the clearly predominant means by which competition has been foreclosed in the Relevant Product Market.

151. Even if price were deemed to be the clearly predominant means by which competition has been foreclosed, when the total amount of discounts and rebates that J&J offers to insurers and providers under the contracts described herein, including multi-product bundled contracts, is attributed to the portion of Remicade sales that is contestable by a biosimilar like Inflectra, J&J is pricing Remicade below its own average variable cost.

152. As a result of J&J's conduct, and the harm to competition caused by that conduct, Plaintiffs and the Classes have suffered substantial and continuing injuries.

COUNT III

Violation of §1 of the Sherman Act, 15 U.S.C. §1
(Unreasonable Restraint of Trade)
(On Behalf of the Injunctive Class)

153. Plaintiffs repeat and reallege each of the foregoing paragraphs of this complaint and incorporate them by reference as though set forth in full herein.

154. J&J has entered into agreements in the Relevant Product Market in violation of §1 of the Sherman Act.

155. Through the scheme described above, and by other conduct likely to be revealed in discovery, J&J has willfully and unlawfully entered into agreements in restraint of trade that excluded would-be competitors from the Relevant Product Market and caused Plaintiffs and the Classes to pay increased prices for infliximab and its biosimilars.

156. J&J's scheme has stifled competition in the Relevant Product Market and thwarted Congress's purpose in enacting the BPCIA.

157. Among other things, given that: (a) J&J imposed explicit conditions that insurers and providers eliminate (or almost completely curtail) their dealings with infliximab biosimilars, and (b) J&J's ASP for Remicade has actually increased since biosimilars entered the market, J&J's pricing is not the clearly predominant means by which competition has been foreclosed in the Relevant Product Market.

158. As a result of J&J's conduct, and the harm to competition caused by that conduct, Plaintiffs and the Classes have suffered substantial and continuing injuries.

COUNT IV

Violation of §3 of the Clayton Act, 15 U.S.C. §14
(Unlawful Exclusive Dealing)
(On Behalf of the Injunctive Class)

159. Plaintiffs repeat and reallege each of the foregoing paragraphs of this complaint and incorporate them by reference as though set forth in full herein.

160. J&J's agreements with insurers and providers are agreements to fix prices and grant discounts or rebates on the condition, agreement or understanding that the providers or insurers would not use or deal with the goods of J&J's infliximab competitors, including Pfizer and Samsung.

161. Through the scheme described above, and by other conduct likely to be revealed in discovery, J&J has willfully and unlawfully entered into agreements in restraint of trade that excluded would-be competitors from the Relevant Product Market and caused payors to pay increased prices for infliximab and its biosimilars.

162. As a result of J&J's conduct, and the harm to competition caused by that conduct, Plaintiffs and the Injunctive Classes have suffered substantial and continuing injuries.

COUNT V

Violation of State Antitrust Statutes
(On Behalf of Plaintiffs and the State Damages Classes Related to Monopolization)[12]

163. Plaintiffs repeat and reallege each of the foregoing paragraphs of this complaint and incorporates them by reference as though set forth in full herein.

164. By engaging in the foregoing conduct, Defendants violated the following state antitrust laws:

165. **Arizona:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Arizona.

(b) Defendants' conduct had the following effects: Arizona purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Arizona commerce.

(d) Defendants' violations of Arizona law were flagrant.

(e) As a direct and proximate result of Defendants' unlawful conduct, Arizona purchasers have been injured in their business and property and are threatened with further injury.

[12] Plaintiffs have complied with the requirements regarding notice to Attorneys General, where applicable. Plaintiffs have also complied with demand requirements of Defendants, where applicable.

(f) By reason of the foregoing, Defendants have violated Ariz. Rev. Stat. Ann. §44-1402, *et seq*. Accordingly, Arizona purchasers seek all forms of relief available under Ariz. Rev. Stat. Ann. §44-1402, *et seq*.

166. **California:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in California.

(b) Defendants' conduct had the following effects: California purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected California commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, California purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Cal. Bus. & Prof. Code §16720, *et seq*. Accordingly, California purchasers seek all forms of relief available under Cal. Bus. & Prof. Code §16720, *et seq*.

167. **District of Columbia:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in the District of Columbia.

(b) Defendants' conduct had the following effects: District of Columbia purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected District of Columbia commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, District of Columbia purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated D.C. Code §28-4509(a). Accordingly, District of Columbia purchasers seek all forms of relief available under D.C. Code §28-4509(a).

168. **Hawaii:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Hawaii.

(b) Defendants' conduct had the following effects: Hawaii purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Hawaii commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Hawaii purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Haw. Rev. Stat. §480-3, *et seq*. Accordingly, Hawaii purchasers seek all forms of relief available under Haw. Rev. Stat. §480-3, *et seq*.

169. **Iowa:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Iowa.

(b) Defendants' conduct had the following effects: Iowa purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Iowa commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Iowa purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Iowa Code §553.2, *et seq*. Accordingly, Iowa purchasers seek all forms of relief available under Iowa Code §553.2, *et seq*.

170. **Kansas:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Kansas.

(b) Defendants' conduct had the following effects: Kansas purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Kansas commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Kansas purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Kan. Stat. Ann. §50-101, *et seq*. Accordingly, Kansas purchasers seek all forms of relief available under Kan. Stat. Ann. §50-101, *et seq*.

171. **Maine:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Maine.

(b) Defendants' conduct had the following effects: Maine purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Maine commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Maine purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Me. Stat. tit. 10, §1101, *et seq*. Accordingly, Maine purchasers seek all forms of relief available under Me. Stat. tit. 10, §1101, *et seq*.

172. **Michigan:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Michigan.

(b) Defendants' conduct had the following effects: Michigan purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Michigan commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Michigan purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Mich. Comp. Laws §445.771, *et seq*. Accordingly, Michigan purchasers seek all forms of relief available under Mich. Comp. Laws §445.771, *et seq*.

173. **Minnesota:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Minnesota.

(b) Defendants' conduct had the following effects: Minnesota purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Minnesota commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Minnesota purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Minn. Stat. §325D.57, *et seq*. Accordingly, Minnesota purchasers seek all forms of relief available under Minn. Stat. §325D.57, *et seq*.

174. **Mississippi:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Mississippi.

(b) Defendants' conduct had the following effects: Mississippi purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Mississippi commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Mississippi purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Miss. Code Ann. §75-21-9, *et seq*. Accordingly, Mississippi purchasers seek all forms of relief available under Miss. Code Ann. §75-21-9, *et seq*.

175. **Nebraska:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Nebraska.

(b) Defendants' conduct had the following effects: Nebraska purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Nebraska commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Nebraska purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Neb. Rev. Stat. §§59-801, 59-802, *et seq.* Accordingly, Nebraska purchasers seek all forms of relief available under Neb. Rev. Stat. §§59-801, 59-802, *et seq*.

176. **Nevada:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Nevada.

(b) Defendants' conduct had the following effects: Nevada purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Nevada commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Nevada purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Nev. Rev. Stat. §598A.210(2), *et seq.* Accordingly, Nevada purchasers seek all forms of relief available under Nev. Rev. Stat. §598A.210(2), *et seq*.

177. **New Hampshire:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in New Hampshire.

(b) Defendants' conduct had the following effects: New Hampshire purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected New Hampshire commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, New Hampshire purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated N.H. Rev. Stat. Ann. §356:11(II), *et seq.* Accordingly, New Hampshire purchasers seek all forms of relief available under N.H. Rev. Stat. Ann. §356:11(II), *et seq*.

178. **New Mexico:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in New Mexico.

(b) Defendants' conduct had the following effects: New Mexico purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected New Mexico commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, New Mexico purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated N.M. Stat. Ann. §§57-1-1, 57-1-2, *et seq.* Accordingly, New Mexico purchasers seek all forms of relief available under N.M. Stat. Ann. §§57-1-1 and 57-1-2, *et seq*.

179. **New York:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in New York.

(b) Defendants' conduct had the following effects: New York purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected New York commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, New York purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated N.Y. Gen. Bus. Law §340, *et seq*. Accordingly, New York purchasers seek all forms of relief available under N.Y. Gen. Bus. Law §349, *et seq*.

180. **North Carolina:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in North Carolina.

(b) Defendants' conduct had the following effects: North Carolina purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected North Carolina commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, North Carolina purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated N.C. Gen. Stat. §75-1, *et seq.* Accordingly, North Carolina purchasers seek all forms of relief available under N.C. Gen. Stat. §75-1, *et seq*.

181. **North Dakota:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in North Dakota.

(b) Defendants' conduct had the following effects: North Dakota purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected North Dakota commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, North Dakota purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated N.D. Cent. Code §§51-08.1-01-02, *et seq.* Accordingly, North Dakota purchasers seek all forms of relief available under N.D. Cent. Code. §§51-08.1-01-02, *et seq*.

182. **Oregon:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Oregon.

(b) Defendants' conduct had the following effects: Oregon purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Oregon commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Oregon purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Or. Rev. Stat. §646.705, *et seq.* Accordingly, Oregon purchasers seek all forms of relief available under Or. Rev. Stat. §646.705, *et seq*.

183. **Rhode Island:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Rhode Island.

(b) Defendants' conduct had the following effects: Rhode Island purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Rhode Island commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Rhode Island purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated R.I. Gen. Laws §6-36-4, *et seq.* Accordingly, Rhode Island purchasers seek all forms of relief available under R.I. Gen. Laws §6-36-4, *et seq.*

184. **South Dakota:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in South Dakota.

(b) Defendants' conduct had the following effects: South Dakota purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected South Dakota commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, South Dakota purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated S.D. Codified Laws §§37-1-3.1, 37-1-3.2, *et seq.* Accordingly, South Dakota purchasers seek all forms of relief available under S.D. Codified Laws §37-1-14-3, *et seq*.

185. **Tennessee:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Tennessee.

(b) Defendants' conduct had the following effects: Tennessee purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Tennessee commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Tennessee purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Tenn. Code Ann. §47-25-106, *et seq.* Accordingly, Tennessee purchasers seek all forms of relief available under Tenn. Code Ann. §47-25-101, *et seq*.

186. **U.S. Virgin Islands:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in the U.S. Virgin Islands.

(b) Defendants' conduct had the following effects: U.S. Virgin Islands purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected U.S. Virgin Islands commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, U.S. Virgin Islands purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated V.I. Code Ann. tit. 11, §1507(4), *et seq.* Accordingly, U.S. Virgin Islands purchasers seek all forms of relief available under V.I. Code Ann. tit. 11, §1507(4), *et seq*.

187. **Utah:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Utah.

(b) Defendants' conduct had the following effects: Utah purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Utah commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Utah purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Utah Code Ann. §76-10-3101, *et seq.* Accordingly, Utah purchasers seek all forms of relief available under Utah Code Ann. §76-10-3101, *et seq*.

188. **West Virginia:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in West Virginia.

(b) Defendants' conduct had the following effects: West Virginia purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected West Virginia commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, West Virginia purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated W. Va. Code §47-18-20, *et seq*. Accordingly, West Virginia purchasers seek all forms of relief available under W. Va. Code §47-18-20, *et seq*.

189. **Wisconsin:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Wisconsin.

(b) Defendants' conduct had the following effects: Wisconsin purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Wisconsin commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Wisconsin purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Wis. Stat. §133.03(1), *et seq.* Accordingly, Wisconsin purchasers seek all forms of relief available under Wis. Stat. Ann. §133.03(1), *et seq*.

190. Plaintiffs and members of the State Damages Classes have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Count. Their

injuries consist of being denied the opportunity to purchase lower-priced infliximab and paying higher prices for infliximab than they would have paid in the absence of Defendants' conduct. These injuries are of the type the antitrust laws were designed to prevent and flow from that which makes Defendants' conduct unlawful.

191. Plaintiffs and the State Damages Classes seek damages and multiple damages as permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

COUNT VI

Violation of State Law for Walker Process Fraud Against All Defendants (On Behalf of the State Damages Class)

192. Plaintiffs repeat and reallege each of the foregoing paragraphs of this complaint and incorporates them by reference as though set forth in full herein.

193. Defendants have willfully and unlawfully maintained their monopoly power in the infliximab market from April 5, 2016 through at least the present day by wrongfully asserting patents obtained by fraud to keep competing products (such as those developed by Pfizer and Samsung) from the market – not as a result of providing a superior product, business acumen, or historical accident.

194. Defendants knowingly and intentionally brought suit regarding competing patents knowing that its patents were invalid. It did this in an attempt to maintain its stranglehold on the market for its powerhouse product, Remicade. As detailed above, Defendants brought multiple patent actions against potential competitors. In each of these actions the result was the same: Defendants lost because the courts found the patent to be obvious and covered by a prior patent.

195. Defendants also filed a sham citizen's petition in order to delay entry of competing, lower cost products.

196. Representations from Defendants regarding the non-obviousness of the patent as well as statements in the citizen's petition were material misrepresentations. These statements were made

with the intent to deceive the U.S. Patent & Trademark Office. The misleading statements were made intentionally, not accidentally. Defendants were motivated to obtain a longer period of patent protection, given the large sales of Remicade and the importance of the product to the company.

197. The misrepresentations and omissions by Defendants delayed the entry of competitors.

198. There is no valid procompetitive business justifications for Defendants' conduct and to the extent one is offered, it is pretextual and not cognizable. Any procompetitive benefits of Defendants' conduct do not outweigh the anticompetitive harms.

199. By engaging in this conduct related to patent litigation, Defendants have wrongfully maintained monopoly power in the relevant markets in violation of the following state laws. This violation is in addition to, and a part of, the multifaceted scheme pleaded herein.

200. **Arizona:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Arizona through abuse of the patent process.

(b) Defendants' conduct had the following effects: Arizona purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Arizona commerce. This conduct was flagrant.

(d) As a direct and proximate result of Defendants' unlawful conduct, Arizona purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Ariz. Rev. Stat. Ann. §44-1402, *et seq.* Accordingly, Arizona purchasers seek all forms of relief available under Ariz. Rev. Stat. Ann. §44-1402, *et seq*.

201. **California:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in California through abuse of the patent process.

(b) Defendants' conduct had the following effects: California purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected California commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, California purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Cal. Bus. & Prof. Code §16720, *et seq*. Accordingly, California purchasers seek all forms of relief available under Cal. Bus. & Prof. Code §16720, *et seq*.

202. **District of Columbia:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in the District of Columbia through abuse of the patent process.

(b) Defendants' conduct had the following effects: District of Columbia purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected District of Columbia commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, District of Columbia purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated D.C. Code §28-4509(a). Accordingly, District of Columbia purchasers seek all forms of relief available under D.C. Code §28-4509(a).

203. **Hawaii:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Hawaii through abuse of the patent process.

(b) Defendants' conduct had the following effects: Hawaii purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Hawaii commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Hawaii purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Haw. Rev. Stat. §480-3, *et seq*. Accordingly, Hawaii purchasers seek all forms of relief available under Haw. Rev. Stat. §480-3, *et seq*.

204. **Iowa:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Iowa through abuse of the patent process.

(b) Defendants' conduct had the following effects: Iowa purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Iowa commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Iowa purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Iowa Code §553.2, *et seq*. Accordingly, Iowa purchasers seek all forms of relief available under Iowa Code §553.2, *et seq*.

205. **Kansas:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Kansas through abuse of the patent process.

(b) Defendants' conduct had the following effects: Kansas purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Kansas commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Kansas purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Kan. Stat. Ann. §50-101, *et seq*. Accordingly, Kansas purchasers seek all forms of relief available under Kan. Stat. Ann. §50-101, *et seq*.

206. **Maine:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Maine through abuse of the patent process.

(b) Defendants' conduct had the following effects: Maine purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Maine commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Maine purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Me. Stat. tit. 10, §1101, *et seq*. Accordingly, Maine purchasers seek all forms of relief available under Me. Stat. tit. 10, §1101, *et seq*.

207. **Michigan:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Michigan through abuse of the patent process.

(b) Defendants' conduct had the following effects: Michigan purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Michigan commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Michigan purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Mich. Comp. Laws §445.771, *et seq*. Accordingly, Michigan purchasers seek all forms of relief available under Mich. Comp. Laws §445.771, *et seq*.

208. **Minnesota:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Minnesota through abuse of the patent process.

(b) Defendants' conduct had the following effects: Minnesota purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Minnesota commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Minnesota purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Minn. Stat. §325D.57, *et seq*. Accordingly, Minnesota purchasers seek all forms of relief available under Minn. Stat. §325D.57, *et seq*.

209. **Mississippi:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Mississippi through abuse of the patent process.

(b) Defendants' conduct had the following effects: Mississippi purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Mississippi commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Mississippi purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Miss. Code Ann. §75-21-9, *et seq*. Accordingly, Mississippi purchasers seek all forms of relief available under Miss. Code Ann. §75-21-9, *et seq*.

210. **Nebraska:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Nebraska through abuse of the patent process.

(b) Defendants' conduct had the following effects: Nebraska purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Nebraska commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Nebraska purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Neb. Rev. Stat. §§59-801, 59-802, *et seq*. Accordingly, Nebraska purchasers seek all forms of relief available under Neb. Rev. Stat. §§59-801, 59-802, *et seq*.

211. **Nevada:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Nevada through abuse of the patent process.

(b) Defendants' conduct had the following effects: Nevada purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Nevada commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Nevada purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Nev. Rev. Stat. §598A.210(2), *et seq*. Accordingly, Nevada purchasers seek all forms of relief available under Nev. Rev. Stat. §598A.210(2), *et seq*.

212. **New Hampshire:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in New Hampshire through abuse of the patent process.

(b) Defendants' conduct had the following effects: New Hampshire purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected New Hampshire commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, New Hampshire purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated N.H. Rev. Stat. Ann. §356:11(II), *et seq*. Accordingly, New Hampshire purchasers seek all forms of relief available under N.H. Rev. Stat. Ann. §356:11(II), *et seq*.

213. **New Mexico:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in New Mexico through abuse of the patent process.

(b) Defendants' conduct had the following effects: New Mexico purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected New Mexico commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, New Mexico purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated N.M. Stat. Ann. §57-1-1, *et seq*. Accordingly, New Mexico purchasers seek all forms of relief available under N.M. Stat. Ann. §57-1-1, *et seq*.

214. **New York:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in New York through abuse of the patent process.

(b) Defendants' conduct had the following effects: New York purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected New York commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, New York purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated N.Y. Gen. Bus. Law §340, *et seq*. Accordingly, New York purchasers seek all forms of relief available under N.Y. Gen. Bus. Law §340, *et seq*.

215. **North Carolina:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in North Carolina through abuse of the patent process.

(b) Defendants' conduct had the following effects: North Carolina purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected North Carolina commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, North Carolina purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated N.C. Gen. Stat. §75-1, *et seq*. Accordingly, North Carolina purchasers seek all forms of relief available under N.C. Gen. Stat. §75-16, *et seq*.

216. **North Dakota:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in North Dakota through abuse of the patent process.

(b) Defendants' conduct had the following effects: North Dakota purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected North Dakota commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, North Dakota purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated N.D. Cent. Code §§51-08.1-01-02 *et seq*. Accordingly, North Dakota purchasers seek all forms of relief available N.D. Cent. Code §§51-08.1-01-02, *et seq*.

217. **Oregon:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Oregon through abuse of the patent process.

(b) Defendants' conduct had the following effects: Oregon purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Oregon commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Oregon purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Or. Rev. Stat. §646.705 *et seq*. Accordingly, Oregon purchasers seek all forms of relief available under Or. Rev. Stat. §646.705 *et seq*.

218. **Rhode Island:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Rhode Island through abuse of the patent process.

(b) Defendants' conduct had the following effects: Rhode Island purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Rhode Island commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Rhode Island purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated R.I. Gen. Laws §6-36-4, *et seq*. Accordingly, Rhode Island purchasers seek all forms of relief available under R.I. Gen. Laws §6-36-4, *et seq*.

219. **South Dakota:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in South Dakota through abuse of the patent process.

(b) Defendants' conduct had the following effects: South Dakota purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected South Dakota commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, South Dakota purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated S.D. Codified Laws §37-1-3.1, *et seq*. Accordingly, South Dakota purchasers seek all forms of relief available under S.D. Codified Laws §37-1-3.1, *et seq*.

220. **Tennessee:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Tennessee through abuse of the patent process.

(b) Defendants' conduct had the following effects: Tennessee purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Tennessee commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Tennessee purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Tenn. Code Ann. §47-25-101, *et seq*. Accordingly, Tennessee purchasers seek all forms of relief available under Tenn. Code Ann. §47-25-101, *et seq*.

221. **U.S. Virgin Islands:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in the U.S. Virgin Islands through abuse of the patent process.

(b) Defendants' conduct had the following effects: U.S. Virgin Islands purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected U.S. Virgin Islands commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, U.S. Virgin Islands purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated V.I. Code Ann. tit. 11, §1507(4), *et seq*. Accordingly, U.S. Virgin Islands purchasers seek all forms of relief available under V.I. Code Ann. tit. 11, §1507(4), *et seq*.

222. **Utah:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Utah through abuse of the patent process.

(b) Defendants' conduct had the following effects: Utah purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Utah commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Utah purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Utah Code Ann. §76-10-3101, *et seq*. Accordingly, Utah purchasers seek all forms of relief available under Utah Code Ann. §76-10-3101, *et seq*.

223. **West Virginia:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in West Virginia through abuse of the patent process.

(b) Defendants' conduct had the following effects: West Virginia purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected West Virginia commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, West Virginia purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated W. Va. Code §47-18-20, *et seq*. Accordingly, West Virginia purchasers seek all forms of relief available under W. Va. Code §47-18-20, *et seq*.

224. **Wisconsin:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Wisconsin through abuse of the patent process.

(b) Defendants' conduct had the following effects: Wisconsin purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Wisconsin commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Wisconsin purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Wis. Stat. §133.03(1), *et seq*. Accordingly, Wisconsin purchasers seek all forms of relief available under Wis. Stat. Ann. §133.03(1), *et seq*.

COUNT VII

Violation of State Consumer Protection Statutes (On Behalf of Plaintiffs and the State Damages Classes)

225. Plaintiffs repeat and reallege each of the foregoing paragraphs of this complaint and incorporate them by reference as though set forth in full herein.

226. Defendants engaged in unfair competition, and/or unfair/unconscionable, and/or deceptive acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair and/or unconscionable acts or practices Plaintiffs and members of the State Damages Classes paid higher prices for infliximab.

227. **Arkansas:**

(a) The aforementioned practices by Defendants were and are in violation of the Arkansas Deceptive Trade Practices Act, Ark. Code Ann. §4-88-101, *et seq.*

(b) Defendants monopolized trade or commerce in the infliximab market, a substantial part of which occurred within Arkansas.

(c) Defendants established, maintained or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the Relevant Product Market, a substantial part of which occurred within Arkansas, for the purpose of excluding competition or controlling, fixing or maintaining prices in the infliximab market.

(d) Defendants' conduct was unfair, unconscionable or deceptive within the conduct of commerce within the State of Arkansas.

(e) Defendants' conduct misled consumers, withheld material facts and resulted in material misrepresentations to Plaintiffs and members of the State Damages Classes.

(f) Defendants' unlawful conduct substantially affected Arkansas's trade and commerce.

(g) Defendants' conduct was willful.

(h) As a direct and proximate cause of Defendants' unlawful conduct, the Plaintiffs and members of the State Damages Classes have been injured in their business or property and are threatened with further injury.

(i) By reason of the foregoing, Plaintiffs are entitled to seek all forms of relief, including actual damages plus reasonable attorneys' fees under Ark. Code Ann. §4-88-113.

228. **California:**

(a) The violations of federal antitrust law set forth above also constitute violations of Cal. Bus. & Prof. Code §17200, *et seq*. ("UCL").

(b) Defendants have engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the UCL by engaging in the acts and practices specified above.

(c) This claim is instituted pursuant to Cal. Bus. & Prof. Code §§17203 and 17204, to obtain restitution from these Defendants for acts, as alleged herein, that violated the UCL.

(d) The Defendants' conduct as alleged herein violated the UCL. The acts, omissions, misrepresentations, practices and non-disclosures of Defendants, as alleged herein, constituted a common, continuous and continuing course of conduct of unfair competition by means of unfair, unlawful and/or fraudulent business acts or practices within the meaning of the UCL, including, but not limited to, the following: (1) the violations of §§1 and 2 of the Sherman Act, as set forth above; and (2) the violations of Cal. Bus. & Prof. Code §16720, *et seq.*, set forth above.

(e) Defendants' acts, omissions, misrepresentations, practices and non-disclosures, as described above, whether or not in violation of Cal. Bus. & Prof. Code §16720, *et seq*., and whether or not concerted or independent acts, are otherwise unfair, unconscionable, unlawful or fraudulent.

(f) Plaintiffs and members of the State Damages Classes are entitled to full restitution and/or disgorgement of all revenues, earnings, profits, compensation and benefits that may have been obtained by Defendants as a result of such business acts or practices.

(g) The illegal conduct alleged herein is continuing and there is no indication that Defendants will not continue such activity into the future.

(h) The unlawful and unfair business practices of Defendants, and each of them, as described above, has caused and continues to cause Plaintiffs and members of the State Damages Classes to pay supracompetitive and artificially inflated prices for infliximab sold in California. Plaintiffs and the members of the State Damages Classes suffered injury in fact and lost money or property as a result of such unfair competition.

(i) The conduct of Defendants as alleged herein violates Cal. Bus. & Prof. Code §17200, *et seq*.

(j) As alleged in this complaint, Defendants have been unjustly enriched as a result of their wrongful conduct and by Defendants' unfair competition. Plaintiffs and members of the State Damages Classes are accordingly entitled to equitable relief, including restitution and/or disgorgement of all revenues, earnings, profits, compensation and benefits that may have been obtained by Defendants as a result of such business practices, pursuant to the Cal. Bus. & Prof. Code, §§17203 and 17204.

229. **District of Columbia:**

(a) Defendants have engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of D.C. Code §28-3901, *et seq.*

(b) Defendants agreed to, and did in fact, act in restraint of trade or commerce by affecting, fixing, controlling and/or maintaining, at artificial and/or non-competitive levels, the prices at which infliximab was sold, distributed or obtained in the District of Columbia.

(c) During the Class Period, Defendants' illegal conduct substantially affected District of Columbia commerce and consumers. The foregoing conduct constitutes "unlawful trade practices," within the meaning of D.C. Code §28-3904.

(d) Plaintiffs and members of the State Damages Classes were not aware of Defendants' monopolization and were therefore unaware that they were being unfairly and illegally overcharged.

(e) Defendants had the sole power to set that price and Plaintiffs and members of the State Damages Classes had no power to negotiate a lower price. Moreover, Plaintiffs and members of the State Damages Classes lacked any meaningful choice in purchasing infliximab because they were unaware of the unlawful overcharge, and there was no alternative source of supply through which Plaintiffs and members of the State Damages Classes could avoid the overcharges.

(f) Defendants' conduct with regard to sales of infliximab, including their monopolization of infliximab, which caused prices of infliximab to be at supracompetitive levels and overcharged consumers, was substantively unconscionable because it was one-sided and unfairly benefited Defendants at the expense of Plaintiffs and the public. Defendants took grossly unfair advantage of Plaintiffs and members of the State Damages Classes.

(g) The suppression of competition that has resulted from Defendants' monopolization has ultimately resulted in unconscionably higher prices for purchasers so that there was a gross disparity between the price paid and the value received for infliximab.

(h) Defendants' unlawful conduct had the following effects: (1) infliximab price competition was restrained, suppressed and eliminated throughout the District of Columbia; (2) infliximab prices were raised, fixed, maintained and stabilized at artificially high levels throughout the District of Columbia; (3) Plaintiffs and members of the State Damages Classes were deprived of free and open competition; and (4) Plaintiffs and members of the State Damages Classes paid supracompetitive, artificially inflated prices for infliximab.

(i) As a direct and proximate result of Defendants' conduct, Plaintiffs and members of the State Damages Classes have been injured and are threatened with further injury.

(j) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code §28-3901, *et seq*., and, accordingly, Plaintiffs and members of the State Damages Classes seek all relief available under that statute.

230. **Florida:**

(a) The aforementioned practices by Defendants were and are in violation of the Florida Deceptive and Unfair Trade Practices Act ("FDUTPA"), Fla. Stat. §501.201, *et seq*.

(b) The FDUTPA defines "[c]onsumer" as "an individual; child, by and through its parent or legal guardian; business; firm; association; joint venture; partnership; estate; trust; business trust; syndicate; fiduciary; corporation; . . . or any other group or combination." Plaintiffs and the members of the State Damages Classes are "[c]onsumers" within the meaning of Fla. Stat. §501.203(7).

(c) The FDUTPA defines "[t]rade or commerce" as:

> [T]he advertising, soliciting, providing, offering, or distributing, whether by sale, rental, or otherwise, of any good or service, or any property, whether tangible or intangible, or any other article, commodity, or thing of value, wherever situated. "Trade or commerce" shall include the conduct of any trade or commerce, however denominated, including any nonprofit or not-for-profit person or activity.

Fla. Stat. §501.203(8). The advertising, soliciting, offering, selling and furnishing of infliximab by Defendants to Plaintiffs and the members of the State Damages Classes is "[t]rade or commerce" within the meaning of the FDUTPA. Fla. Stat. §501.203(8).

(d) The FDUTPA provides that "[u]nfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful." Fla. Stat. §501.204(1). Defendants' acts as alleged in this complaint are unconscionable, illegal, unfair and/or deceptive.

(e) The unconscionable, illegal, unfair and deceptive acts and practices of Defendants are violative of the provisions of FDUTPA. Plaintiffs and the members of the State Damages Classes have suffered actual damage for which they are entitled to relief pursuant to Fla. Stat. §501.211(2).

(f) Plaintiffs, individually and in their representative capacities, are entitled to recover reasonable attorneys' fees pursuant to Fla. Stat. §501.2105, upon prevailing in this matter.

231. **Hawaii:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by affecting, fixing, controlling and/or maintaining, at artificial and/or non-competitive levels, the prices at which infliximab was sold in Hawaii.

(b) The foregoing conduct constitutes "unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce" within the meaning of Haw. Rev. Stat. §480-2(a). During the Class Period, Defendants' illegal conduct substantially affected Hawaii commerce and consumers.

(c) Defendants' unlawful conduct had the following effects: (1) infliximab price competition was restrained, suppressed and eliminated throughout Hawaii; (2) infliximab prices were raised, fixed, maintained and stabilized at artificially high levels throughout Hawaii; (3) Plaintiffs and members of the State Damages Classes were deprived of free and open competition; and (4) Plaintiffs and members of the State Damages Classes paid supracompetitive, artificially inflated prices for infliximab.

(d) As a direct and proximate result of Defendants' conduct, Plaintiffs and members of the State Damages Classes have been injured and are threatened with further injury.

(e) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. §480-2. Accordingly, Plaintiffs and members of the State Damages Classes seek all relief available under Haw. Rev. Stat. §480-1, *et seq*.

232. **Montana:**

(a) Defendants have engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the Montana Unfair Trade Practices and Consumer Protection Act of 1970, Mont. Code Ann. §30-14-103, *et seq*., and §30-14-201, *et seq*.

(b) Defendants' unlawful conduct had the following effects: (1) infliximab price competition was restrained, suppressed and eliminated throughout Montana; (2) infliximab prices were raised, fixed, maintained and stabilized at artificially high levels throughout Montana; (3) Plaintiffs and members of the State Damages Classes were deprived of free and open competition; and (4) Plaintiffs and members of the State Damages Classes paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants marketed, sold or distributed infliximab in Montana, and Defendants' illegal conduct substantially affected Montana commerce and consumers. As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and members of the State Damages Classes have been injured and are threatened with further injury. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code Ann., §30-14-103, *et seq*., and §30-14-201, *et seq*., and, accordingly, Plaintiffs and members of the State Damages Classes seek all relief available under that statute.

233. **Nebraska:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce in Nevada by affecting, fixing, controlling and/or maintaining, at artificial and/or non-competitive levels, the prices at which infliximab was sold, distributed or obtained in Nebraska.

(b) The foregoing conduct constitutes "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce" within the meaning of Neb. Rev. Stat. §59-1602.

(c) During the Class Period, Defendants' illegal conduct substantially affected Nebraska's commerce and consumers.

(d) Defendants' unlawful conduct had the following effects: (1) infliximab price competition was restrained, suppressed and eliminated throughout Nebraska; (2) price competition for infliximab was restrained, suppressed and eliminated throughout Nebraska; (3) infliximab prices were raised, fixed, maintained and stabilized at artificially high levels throughout Nebraska; (4) Plaintiffs and members of the State Damages Classes were deprived of free and open competition; and (5) Plaintiffs and members of the State Damages Classes paid supracompetitive, artificially inflated prices for infliximab.

(e) As a direct and proximate result of Defendants' conduct, Plaintiffs and members of the State Damages Classes have been injured and are threatened with further injury.

(f) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. §59-1601, *et seq*., and accordingly, Plaintiffs and members of the Classes seek all relief available under that statute.

234. **Nevada:**

(a) Defendants have engaged in unfair competition or unfair, unconscionable or deceptive acts or practices in violation of the Nevada Deceptive Trade Practices Act, Nev. Rev. Stat. §598.0903, *et seq.* Defendants agreed to, and did in fact, act in restraint of trade or commerce in Nevada, by affecting, fixing, controlling and/or maintaining, at artificial and noncompetitive levels, the prices at which infliximab was sold, distributed or obtained in Nevada.

(b) Defendants deliberately failed to disclose material facts to Plaintiffs and members of the State Damages Classes concerning Defendants' unlawful activities and artificially inflated prices for infliximab.

(c) Defendants misrepresented to all purchasers during the Class Period that Defendants' infliximab prices were competitive and fair.

(d) Defendants' unlawful conduct had the following effects: (1) infliximab price competition was restrained, suppressed and eliminated throughout Nevada; (2) infliximab prices were raised, fixed, maintained and stabilized at artificially high levels throughout Nevada; (3) Plaintiffs and members of the State Damages Classes were deprived of free and open competition; and (4) Plaintiffs and members of the State Damages Classes paid supracompetitive, artificially inflated prices for infliximab.

(e) During the Class Period, Defendants' illegal conduct had a substantial effect on Nevada commerce and consumers. As a direct and proximate result of Defendants' violations of law, Plaintiffs and members of the State Damages Classes suffered an ascertainable loss of money or property as a result of Defendants' use or employment of unconscionable and deceptive commercial practices as set forth above. That loss was caused by Defendants' willful and deceptive conduct, as described herein.

(f) Defendants' deception, including their affirmative misrepresentations and omissions concerning the price of infliximab, likely misled all purchasers acting reasonably under the circumstances to believe that they were purchasing infliximab at prices set by a free and fair market. Defendants' misleading conduct and unconscionable activities constitute violations of Nev. Rev. Stat. §598.0903, *et seq*.

(g) Plaintiffs and members of the State Damages Classes seek all relief available under that statute.

235. **New Hampshire:**

(a) Defendants have engaged in unfair competition or unfair, unconscionable or deceptive acts or practices in violation of the New Hampshire Consumer Protection Act, N.H. Rev. Stat. Ann. §358-A:1, *et seq.*

(b) Defendants' unlawful conduct had the following effects: (1) infliximab price competition was restrained, suppressed and eliminated throughout New Hampshire; (2) infliximab prices were raised, fixed, maintained and stabilized at artificially high levels throughout New Hampshire; (3) Plaintiffs and members of the State Damages Classes were deprived of free and open competition; and (4) Plaintiffs and members of the State Damages Classes paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants marketed, sold or distributed infliximab in New Hampshire, and Defendants' illegal conduct substantially affected New Hampshire commerce and consumers.

(d) As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and members of the State Damages Classes have been injured.

(e) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. Ann. §358-A:1, *et seq.*, and, accordingly, Plaintiffs and members of the State Damages Classes seek all relief available under that statute.

236. **New Mexico:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by affecting, fixing, controlling and/or maintaining, at artificial and/or non-competitive levels, the prices at which infliximab was sold in New Mexico.

(b) The foregoing conduct constitutes "[u]nfair or deceptive trade practices and unconscionable trade practices in the conduct of any trade or commerce" within the meaning of

N.M. Stat. Ann. §57-12-3, in that such conduct resulted in a gross disparity between the value received by New Mexico purchasers and the prices paid by them for infliximab as set forth in N.M. Stat. Ann. §57-12-2E.

(c) During the Class Period, Defendants' illegal conduct substantially affected New Mexico's commerce and consumers.

(d) Defendants' unlawful conduct had the following effects: (1) price competition for infliximab was restrained, suppressed and eliminated throughout New Mexico; (2) infliximab prices were raised, fixed, maintained and stabilized at artificially high levels throughout New Mexico; (3) Plaintiffs and members of the State Damages Classes were deprived of free and open competition; and (4) Plaintiffs and members of the State Damages Classes paid supracompetitive, artificially inflated prices for infliximab.

(e) As a direct and proximate result of Defendants' conduct, Plaintiffs and members of the State Damages Classes have been injured and are threatened with further injury.

(f) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. §57-12-1, *et seq*., and accordingly Plaintiffs and members of the State Damages Classes seek all relief available under that statute.

237. **New York:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by affecting, fixing, controlling and/or maintaining, at artificial and/or non-competitive levels, the prices at which infliximab was sold in New York.

(b) Defendants' illegal conduct substantially affected New York's commerce and consumers.

(c) The conduct of Defendants as described herein constitutes consumer-oriented deceptive acts or practices within the meaning of N.Y. Gen. Bus. Law §349, which resulted in

consumer injury and had a broad adverse impact on the public at large, and harmed the public interest of the State of New York in an honest marketplace in which economic activity is conducted in a competitive manner.

(d) As consumers, New York purchasers were targets of the conspiracy.

(e) Defendants made public statements about the price of infliximab that Defendants knew would be seen by New York purchasers. Such statements either omitted material information that rendered the statements made materially misleading or affirmatively misrepresented the real cause of price increases for infliximab. Defendants alone possessed material information that was relevant to consumers, but failed to provide that information.

(f) Because of Defendants' unlawful trade practices in the State of New York, there was a broad impact on New York purchasers who indirectly purchased infliximab. New York purchasers have been injured because they have paid more for infliximab than they would have paid in the absence of Defendants' unlawful trade acts and practices and they are threatened with further injury.

(g) Because of Defendants' unlawful trade practices in the State of New York, New York purchasers who indirectly purchased infliximab were misled into believing that they were paying a fair price for infliximab, or that the price increases for infliximab were for valid business reasons.

(h) Defendants knew that their unlawful trade practices with respect to the pricing of infliximab would have an impact on New York purchasers and not just Defendants' direct customers.

(i) Defendants knew that their unlawful trade practices with respect to the pricing of infliximab would have a broad impact, causing members of the State Damages Classes who

indirectly purchased infliximab to be injured by paying more for infliximab than they would have paid in the absence of Defendants' unlawful trade acts and practices.

(j) During the Class Period, each of the Defendants named herein, directly or indirectly through affiliates they dominated and controlled, manufactured, sold and/or distributed infliximab in New York.

(k) Plaintiffs and the State Damages Classes seek actual damages for their injuries caused by these violations in an amount to be determined at trial.

238. **North Carolina:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by affecting, fixing, controlling and/or maintaining, at artificial and/or non-competitive levels, the prices at which infliximab was sold in North Carolina.

(b) Defendants also took efforts to conceal their agreements from North Carolina purchasers.

(c) The conduct of Defendants as described herein constitutes consumer-oriented deceptive acts or practices within the meaning of N.C. Gen. Stat. §75-1.1, *et seq*., which resulted in consumer injury and had a broad adverse impact on the public at large and harmed the public interest of North Carolina consumers in an honest marketplace in which economic activity is conducted in a competitive manner.

(d) During the Class Period, Defendants' illegal conduct substantially affected North Carolina's commerce and consumers.

(e) Defendants' unlawful conduct had the following effects: (1) infliximab price competition was restrained, suppressed and eliminated throughout North Carolina; (2) infliximab prices were raised, fixed, maintained and stabilized at artificially high levels throughout North

Carolina; (3) North Carolina purchasers were deprived of free and open competition; and (4) North Carolina purchasers paid supracompetitive, artificially inflated prices for infliximab

(f) As a direct and proximate result of Defendants' conduct, North Carolina purchasers have been injured and are threatened with further injury.

(g) During the Class Period, each of the Defendants named herein, directly or indirectly through affiliates they dominated and controlled, manufactured, sold and/or distributed infliximab in North Carolina.

(h) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. §75-1.1, *et seq*., and accordingly, North Carolina purchasers seek all relief available under that statute.

239. **Rhode Island:**

(a) Defendants have engaged in unfair competition or unfair, unconscionable or deceptive acts or practices in violation of the Rhode Island Unfair Trade Practice and Consumer Protection Act, R.I. Gen. Laws §6-13.1, *et seq.*

(b) Members of the State Damages Classes purchased infliximab for personal, family or household purposes.

(c) Defendants agreed to, and did in fact, act in restraint of trade or commerce in a market that includes Rhode Island, by affecting, fixing, controlling and/or maintaining, at artificial and non-competitive levels, the prices at which infliximab was sold, distributed or obtained in Rhode Island.

(d) Defendants deliberately failed to disclose material facts to Plaintiffs and members of the State Damages Classes concerning Defendants' unlawful activities and artificially inflated prices for infliximab.

(e) Defendants owed a duty to disclose such facts, and considering the relative lack of sophistication of the average, non-business purchaser, Defendants breached that duty by their silence.

(f) Defendants misrepresented to all purchasers during the Class Period that Defendants' infliximab prices were competitive and fair. Defendants' unlawful conduct had the following effects: (1) infliximab price competition was restrained, suppressed and eliminated throughout Rhode Island; (2) infliximab prices were raised, fixed, maintained and stabilized at artificially high levels throughout Rhode Island; (3) Plaintiffs and members of the State Damages Classes were deprived of free and open competition; and (4) Plaintiffs and members of the State Damages Classes paid supracompetitive, artificially inflated prices for infliximab.

(g) Defendants' illegal conduct substantially affected Rhode Island commerce and consumers.

(h) As a direct and proximate result of Defendants' violations of law, Plaintiffs and members of the State Damages Classes suffered an ascertainable loss of money or property as a result of Defendants' use or employment of unconscionable and deceptive commercial practices as set forth above. That loss was caused by Defendants' willful and deceptive conduct, as described herein. Defendants' deception, including their affirmative misrepresentations and omissions concerning the price of infliximab, likely misled all purchasers acting reasonably under the circumstances to believe that they were purchasing infliximab at prices set by a free and fair market. Defendants' affirmative misrepresentations and omissions constitute information important to Plaintiffs and members of the State Damages Classes as they related to the cost of infliximab they purchased.

(i) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws §6-13.1-1, *et seq*., and, accordingly, Plaintiffs and members of the State Damages Classes seek all relief available under that statute.

240. **Utah:**

(a) Defendants have engaged in unfair competition or unfair, unconscionable or deceptive acts or practices in violation of the Utah Consumer Sales Practices Act, Utah Code Ann. §13-11-1, *et seq*.

(b) Members of the State Damages Classes purchased infliximab for personal, family or household purposes.

(c) Defendants agreed to, and did in fact, act in restraint of trade or commerce in a market that includes Utah, by affecting, fixing, controlling and/or maintaining, at artificial and non-competitive levels, the prices at which infliximab was sold, distributed or obtained in Utah.

(d) Defendants deliberately failed to disclose material facts to Plaintiffs and members of the State Damages Classes concerning Defendants' unlawful activities and artificially inflated prices for infliximab.

(e) Defendants owed a duty to disclose such facts, and considering the relative lack of sophistication of the average, non-business purchaser, Defendants breached that duty by their silence. Defendants misrepresented to all purchasers during the Class Period that Defendants' infliximab prices were competitive and fair. Defendants' unlawful conduct had the following effects: (1) infliximab price competition was restrained, suppressed and eliminated throughout Utah; (2) infliximab prices were raised, fixed, maintained and stabilized at artificially high levels throughout Utah; (3) Plaintiffs and members of the State Damages Classes were deprived of free and open competition; and (4) Plaintiffs and members of the State Damages Classes paid

supracompetitive, artificially inflated prices for infliximab. Defendants' illegal conduct substantially affected Utah commerce and consumers.

(f) As a direct and proximate result of Defendants' violations of law, Plaintiffs and members of the State Damages Classes suffered an ascertainable loss of money or property as a result of Defendants' use or employment of unconscionable and deceptive commercial practices as set forth above and are threatened with further injury. That loss was caused by Defendants' willful and deceptive conduct, as described herein. Defendants' deception, including their affirmative misrepresentations and omissions concerning the price of infliximab, likely misled all purchasers acting reasonably under the circumstances to believe that they were purchasing infliximab at prices set by a free and fair market.

(g) Defendants' affirmative misrepresentations and omissions constitute information important to Plaintiffs and members of the State Damages Classes as they related to the cost of infliximab they purchased. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. §13-11-1, *et seq*., and, accordingly, Plaintiffs and members of the State Damages Classes seek all relief available under that statute and as equity demands.

241. **Vermont:**

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by affecting, fixing, controlling and/or maintaining, at artificial and/or non-competitive levels, the prices at which infliximab was sold in Vermont.

(b) Defendants deliberately failed to disclose material facts to Vermont purchasers concerning Defendants' unlawful activities and artificially inflated prices for infliximab. Defendants owed a duty to disclose such facts, and considering the relative lack of sophistication of the average, non-business consumer, Defendants breached that duty by their silence. Defendants

misrepresented to all consumers during the Class Period that prices for Defendants' infliximab were competitive and fair.

(c) Because of Defendants' unlawful and unscrupulous trade practices in Vermont, Vermont purchasers who indirectly purchased infliximab were misled or deceived into believing that they were paying a fair price for infliximab or that the price increases for infliximab were for valid business reasons.

(d) Defendants' unlawful conduct had the following effects: (1) price competition for infliximab was restrained, suppressed and eliminated throughout Vermont; (2) infliximab prices were raised, fixed, maintained and stabilized at artificially high levels throughout Vermont; (3) Vermont purchasers were deprived of free and open competition; and (4) Vermont purchasers paid supracompetitive, artificially inflated prices for infliximab.

(e) As a direct and proximate result of Defendants' illegal conduct, Vermont purchasers suffered an ascertainable loss of money or property as a result of Defendants' use or employment of unconscionable and deceptive commercial practices as set forth above. That loss was caused by Defendants' willful and deceptive conduct, as described herein.

(f) Defendants' misleading conduct and unconscionable activities constitute unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. tit. 9, ch. 63 §2451, *et seq*., and accordingly, Vermont purchasers seek all relief available under that statute.

242. **West Virginia:**

(a) Defendants have engaged in unfair competition or unfair, unconscionable or deceptive acts or practices in violation of the West Virginia Consumer Credit and Protection Act, W.Va. Code §46A-6-101, *et seq.*

(b) Defendants agreed to, and did in fact, act in restraint of trade or commerce in a market that includes West Virginia, by affecting, fixing, controlling and/or maintaining, at artificial

and non-competitive levels, the prices at which infliximab was sold, distributed or obtained in West Virginia.

(c) Defendants deliberately failed to disclose material facts to Plaintiffs and members of the State Damages Classes concerning Defendants' unlawful activities and artificially inflated prices for infliximab.

(d) Defendants affirmatively misrepresented to all purchasers during the Class Period that Defendants' infliximab prices were competitive and fair.

(e) Defendants' unlawful conduct had the following effects: (1) infliximab price competition was restrained, suppressed and eliminated throughout West Virginia; (2) infliximab prices were raised, fixed, maintained and stabilized at artificially high levels throughout West Virginia; (3) Plaintiffs and members of the State Damages Classes were deprived of free and open competition; and (4) Plaintiffs and members of the State Damages Classes paid supracompetitive, artificially inflated prices for infliximab.

(f) Defendants' illegal conduct substantially affected West Virginia commerce and consumers.

(g) As a direct and proximate result of Defendants' violations of law, Plaintiffs and members of the State Damages Classes suffered an ascertainable loss of money or property as a result of Defendants' use or employment of unconscionable and deceptive commercial practices as set forth above. That loss was caused by Defendants' willful and deceptive conduct, as described herein. Defendants' deception, including their affirmative misrepresentations and omissions concerning the price of infliximab, likely misled all purchasers acting reasonably under the circumstances to believe that they were purchasing infliximab at prices set by a free and fair market.

(h) Defendants' affirmative misrepresentations and omissions constitute information important to Plaintiffs and members of the State Damages Classes as they related to the cost of infliximab they purchased.

(i) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of W.Va. Code §46A-6-101, *et seq*., and, accordingly, Plaintiffs and members of the State Damages Classes seek all relief available under that statute.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request that the Court enter judgment on Plaintiffs' behalf and on behalf of the Classes herein, adjudging and decreeing that:

A. This action may be maintained as a class action under Rule 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure, and reasonable notice of this action, as provided by Rule 23(c)(2) of the Federal Rules of Civil Procedure, be given to each and every member of the Classes.

B. The unlawful conduct alleged herein be adjudged and decreed:

(i) An unreasonable restraint of trade or commerce in violation of §§1 and 2 of the Sherman Act and §3 of the Clayton Act;

(ii) Unlawful monopoly maintenance in violation of the state antitrust and unfair competition and consumer protection laws as set forth herein;

(iii) Unlawful violation of state antitrust and unfair competition and consumer protection laws based on Defendants' wrongdoing in relation to the patent process (Walker process fraud); and

(iv) Unlawful attempted monopoly maintenance in violation of the state antitrust and unfair competition and consumer protection laws as set forth herein.

C. Plaintiffs and the members of the Classes recover damages, to the maximum extent allowed under such laws, and that a judgment in favor of Plaintiffs and the members of the Classes be entered against the Defendants in an amount to be trebled to the extent such laws permit.

D. Plaintiffs and the members of the Classes recover damages, to the maximum extent allowed by such laws, in the form of restitution and/or disgorgement of profits unlawfully gained from them.

E. Defendants, their affiliates, successors, transferees, assignees and other officers, directors, partners, agents and employees thereof, and all other persons acting or claiming to act on their behalf or in concert with them, be permanently enjoined and restrained from, in any manner, continuing, maintaining or renewing the conduct alleged herein, or from entering into any other contract or engaging in any other conduct having a similar purpose or effect, and from adopting or following any practice, plan, program or device having a similar purpose or effect.

F. Plaintiffs and the members of the Classes be awarded restitution, including disgorgement of profits Defendants obtained as a result of their acts of unfair competition and acts of unjust enrichment.

G. Plaintiffs and the members of the Classes be awarded pre- and post- judgment interest as provided by law, and that such interest be awarded at the highest legal rate from and after the date of service of this complaint.

H. Plaintiffs and the members of the Classes recover their costs of suit, including reasonable attorneys' fees, as provided by law.

I. Plaintiffs and members of the Classes have such other and further relief as the case may require and the Court may deem just and proper.

JURY DEMAND

Plaintiffs demand a trial by jury, pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, of all issues so triable.

Dated: February 21, 2018

SHEPHERD, FINKELMAN, MILLER & SHAH, LLP

/s/Jayne A. Goldstein

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